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UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF NEW YORK

MOSAIC HEALTH, INC. and CENTRAL VIRGINIA HEALTH SERVICES, INC., individually and on behalf of all those similarly situated, Plaintiffs, vs. SANOFI-AVENTIS U.S., LLC, ELI LILLY AND COMPANY, LILLY USA, LLC, NOVO NORDISK INC., and ASTRAZENECA PHARMACEUTICALS LP, Defendants.	**FIRST AMENDED <u>COMPLAINT</u>** **Class Action** **Jury Trial Demanded** **6:21-cv-6507 (EAW)**

Plaintiffs Mosaic Health, Inc. and Central Virginia Health Services, Inc. on behalf of themselves and all those similarly situated, by their counsel allege as follows:

INTRODUCTION

1. This case challenges coordination by four drug companies to boost their profits at the expense of the safety-net hospitals and clinics that care for patients who have nowhere else to turn. Those four drug companies—defendants here—should directly compete with each other. Yet, instead of competing for business, they worked together to boost their profits by coordinating to retract a long-standing discount for safety-net hospitals and clinics. That coordination allowed each defendant to individually avoid competitive pressure and prevent

individual market share losses, while restricting safety-net hospitals' abilities to deliver robust and affordable healthcare options to patients. That horizontal agreement was a *per se* violation of state and federal antitrust laws. This antitrust class action seeks injunctive and compensatory relief for the safety-net hospitals and clinics harmed by the drug companies' anti-competitive agreement.

2. The defendants here are four drug companies that dominate three key markets for diabetes treatments. They are: Sanofi-Aventis U.S., LLC (Sanofi); Eli Lilly and Company and Lilly USA, LLC (together, Eli Lilly); Novo Nordisk Inc. (Novo Nordisk); and AstraZeneca Pharmaceuticals LP (AstraZeneca) (collectively, Defendants). They dominate the lucrative diabetes markets for: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. These markets account for billions of dollars of annual U.S. sales for Defendants and, as such, are among the most important drug markets for the Defendants. At the time their conspiracy began, Defendants faced no significant competition, apart from one another, in these multi-billion dollar markets.

3. The discount that Defendants conspired to limit was a special discount offered to safety-net hospitals and clinics, which purchase drugs filled by their patients at retail pharmacies. The discount is calculated by a mathematical formula codified at Section 340B of the Public Health Service Act, 42 U.S.C. § 256b and is known as the 340B Drug Discount. For at least a decade, drug companies offered the 340B Drug Discount to safety-net hospitals and clinics, not only for on-site use but also for purchase and distribution by retail pharmacies. Those pharmacies, typically called contract pharmacies (Contract Pharmacies), have contracts with safety-net providers, which allows the providers to purchase drugs on their own accounts, discounted with the 340B Drug Discount, to be delivered to and dispensed by the Contract

Pharmacies. Drug companies, including Defendants, have argued that their provision of 340B Drug Discounts at Contract Pharmacies is voluntary, not mandated by law. But, for at least a decade, nearly all pharmaceutical companies, including Defendants, had offered safety-net providers drugs at 340B Drug Discounts for dispensing at Contract Pharmacies (Contract Pharmacy 340B Drug Discounts). And, with all pharmaceutical competitors regularly offering Contract Pharmacy 340B Drug Discounts, patients benefitted, because safety-net hospitals and clinics have been able to use savings from those discounts to expand healthcare services and lower healthcare costs for patients.

4. But Defendants, in coordination with one other, departed from that industry-wide practice beginning in the summer of 2020. After a decade of providing Contract Pharmacy 340B Drug Discounts to safety-net providers through their Contract Pharmacies, Defendants—and Defendants alone among hundreds of leading pharmaceutical companies—suddenly, and in coordination with one another, ceased the practice of offering Contract Pharmacy 340B Drug Discounts. So, while nearly every pharmaceutical company in the country continued to offer Contract Pharmacy 340B Drug Discounts, Defendants, competitors with one another primarily as to the lucrative diabetes medications described above, coordinated an historically unprecedented change in 340B pricing practices nearly simultaneously.

5. The Plaintiffs and Class Members harmed by those actions are safety-net hospitals and clinics, which provide healthcare services to low-income and underserved patients, funded in significant part through savings from 340B Drug Discounts. The Plaintiffs are Mosaic Health, Inc. (Mosaic Health) and Central Virginia Health Services, Inc. (CVHS). Mosaic Health is a federally qualified health center (FQHC) comprised of 22 safety-net clinics: Charlotte School Based Health Center; Clinton Family Health; Edison Tech Community Health Center;

Freddie Thomas Health Center; Genesee Health service; John James Audubon Health Center; Martin Luther King Jr. Health Center; Mosaic Health Rushville; Mosaic Health Mount Morris; Mosaic Health Lyons; Mosaic Health Utica; Mosaic Health Utica Dental; Mosaic Health Ilion; Newark Internal Medicine; Riedman Health Center; Unity Dental at St. Mary's; Unity Dental at Ridgeway; Unity Family Medicine at Orchard Street; Unity Family Medicine at St. Mary's; Wolcott Primary Care; Women's Center at Clinton Family; and Women's Center at Rochester General Hospital. CVHS is also a FQHC comprised of 18 safety-net clinics: CVHS Brunswick; CVHS Buckingham; CVHS Caroline; CVHS Charles City; CVHS Charlotte; CVHS Charlottesville; CVHS Children's Dental; CVHS Crimson-Clinic; CVHS Downtown Petersburg; CVHS Farmville; CVHS Fredericksburg; CVHS Hopewell - Prince George; CVHS King William; CVHS Louisa; CVHS Petersburg; CVHS Peterson; CVHS Southern Albemarle; and CVHS Westmoreland. Each of these safety-net clinics is a covered entity participating in the 340B Drug Discount Program with contracts with retail pharmacies. For years, these clinics have obtained Contract Pharmacy 340B Drug Discounts from nearly all drug companies, including Defendants, and have been able to use the resulting savings to expand healthcare options for patients in their communities.

6. Defendants' conspiracy began in the summer of 2020. Through mid-summer, Defendants had spent millions collectively lobbying the federal government (in efforts not challenged here) to limit 340B Drug Discounts with respect to diabetes medicines. A long-running lobbying campaign by drug companies had sought (i) to limit the level of hospital participation in the 340B Program, (ii) to limit which patients could qualify for 340B Drug Discounts, (iii) to require that all discounts be passed through to patients at the point of sale, and/or (iv) to restrict the availability of Contract Pharmacy 340B Drug Discounts. But

Defendants' lobbying efforts failed. That failure became evident on July 24, 2020, when President Trump issued Executive Order 13937 addressing the 340B Drug Discount in the context of insulin medication and injectable epinephrine. The executive order did little to accomplish any of Defendants' goals. As soon as it became clear that Defendants' collective lobbying efforts had failed, Defendants turned to another plan focused on just the last of those goals—collusively eliminating or limiting Contract Pharmacy 340B Drug Discounts for their drugs, most significantly including their drugs dominating rapid-acting analog insulin, long-acting analog insulin, and incretin mimetic sales. Indeed, on July 24, 2020, the very same day that the executive order was issued, the first defendant, AstraZeneca, revealed its intention to restrict Contract Pharmacy 340B Drug Discounts.

7. The other Defendants executed similar plans in short order. While Defendants' Plan A (lobbying the federal government to restrict 340B Drug Discounts) may have been perfectly legal and legitimate, their Plan B (agreeing among themselves to restrict Contract Pharmacy 340B Drug Discounts) was not. The plan worked only with buy-in from each of the other Defendants. If any Defendant had acted alone, it would have risked losing significant market share in the lucrative markets for diabetes treatments; and, over time, safety-net providers could have purchased drugs from that Defendant's competitors to access Contract Pharmacy 340B Drug Discounts to maximize healthcare services and to lower costs for patients. But, by acting together, Defendants safeguarded themselves against competition in the lucrative diabetes medication markets. Defendants' conspiracy has succeeded in raising prices, by eliminating Contract Pharmacy 340B Drug Discounts, while protecting their market position from competition from one another.

8. That conspiracy is doing immense damage to Plaintiffs and other safety-net hospitals and clinics, and, consequently, to the healthcare options available to the patients they serve. Congress gave safety-net hospitals and clinics "access to [340B Drug Discounts] . . . to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Defendants' conspiracy is having the opposite effect—limiting the ability of safety-net hospitals and clinics to reach more patients and provide more healthcare services by causing significant financial shortfalls for Plaintiffs and other safety-net hospitals and clinics alike. The savings that hospitals and clinics generate from Contract Pharmacy 340B Drug Discounts are used, among other things, to expand the medical services available to the communities served by safety-net facilities, especially for the uninsured or underinsured, and to provide charity care or subsidized pharmacy benefits to help meet the healthcare needs of needy patients. Defendants' conspiracy has threatened those services and benefits. Because Defendants' conspiracy violates state and federal antitrust laws, and the common law, Plaintiffs seek class-wide damages, injunctive, and other equitable relief.

PARTIES

9. Plaintiff Mosaic Health, Inc., formerly known as Rochester Primary Care Network, is a nonprofit healthcare organization with its principal place of business in Rochester, New York. Mosaic Health, Inc. is a federally qualified health center that receives funds from the U.S. Department of Health and Human Services, Health Resources and Services Administration to provide healthcare services to people residing in medically underserved areas, regardless of their ability to pay. Mosaic Health, Inc. includes 22 safety-net clinics participating in the 340B Program: Charlotte School Based Health Center; Clinton Family Health; Edison Tech

Community Health Center; Freddie Thomas Health Center; Genesee Health service; John James Audubon Health Center; Martin Luther King Jr. Health Center; Mosaic Health Rushville; Mosaic Health Mount Morris; Mosaic Health Lyons; Mosaic Health Utica; Mosaic Health Utica Dental; Mosaic Health Ilion; Newark Internal Medicine; Riedman Health Center; Unity Dental at St. Mary's; Unity Dental at Ridgeway; Unity Family Medicine at Orchard Street; Unity Family Medicine at St. Mary's; Wolcott Primary Care; Women's Center at Clinton Family; and Women's Center at Rochester General Hospital. Mosaic Health has had contract pharmacy arrangements in place since at least October 2010.

10. Plaintiff Central Virginia Health Services, Inc. is a nonprofit healthcare organization with its principal place of business in New Canton, Virginia. Central Virginia Health Services, Inc. is a federally qualified health center that receives funds from the U.S. Department of Health and Human Services, Health Resources and Services Administration to provide healthcare services to people residing in medically underserved areas, regardless of their ability to pay. CVHS includes 18 safety-net clinics participating in the 340B Program: CVHS Brunswick; CVHS Buckingham; CVHS Caroline; CVHS Charles City; CVHS Charlotte; CVHS Charlottesville; CVHS Children's Dental; CVHS Crimson-Clinic; CVHS Downtown Petersburg; CVHS Farmville; CVHS Fredericksburg; CVHS Hopewell - Prince George; CVHS King William; CVHS Louisa; CVHS Petersburg; CVHS Peterson; CVHS Southern Albemarle; and CVHS Westmoreland. CVHS has had contract pharmacy arrangements in place since at least approximately July 2011.

11. Defendant Sanofi-Aventis U.S., LLC is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. Sanofi-Aventis U.S., LLC is a wholly owned subsidiary of the French company, Sanofi.

12. Defendant Eli Lilly and Company is an Indiana corporation with its principal place of business in Indianapolis, Indiana.

13. Defendant Lilly USA, LLC is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Lilly USA, LLC is a wholly owned subsidiary of Eli Lilly and Company.

14. Defendant Novo Nordisk Inc. is a Delaware corporation with its principal place of business in Plainsboro, New Jersey. Novo Nordisk Inc. is the United States affiliate of the Danish company, Novo Nordisk A/S.

15. Defendant AstraZeneca Pharmaceuticals LP is a Delaware limited partnership with its principal place of business in Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is a wholly owned subsidiary of the English company, AstraZeneca Pharmaceuticals PLC.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over the claims arising under federal antitrust laws under 15 U.S.C. §§ 4, 15, and 26, and 28 U.S.C. §§ 1331 and 1337. This Court has supplemental jurisdiction over the claims arising under State laws under 28 U.S.C. § 1367. This Court also has diversity jurisdiction over this class action of the State law claims under 28 U.S.C. § 1332(d) because the aggregate amount in controversy exceeds $5,000,000, there are more than one hundred Class Members, and Members of the Class are citizens of states different from that of one of the Defendants. Likewise, this Court has diversity jurisdiction over the named Plaintiffs' claims under 28 U.S.C. § 1332(a) because all of the named Plaintiffs are citizens of different States than all of the Defendants and the amount in controversy exceeds $75,000.

17. This Court has personal jurisdiction over Defendants under Rule 4(k)(1)(A) of the Federal Rules of Civil Procedure and NY CPLR § 302 because, *inter alia*, Defendants transact

and do business within the State of New York, contract to supply goods and services within the State of New York, regularly solicit business and derive substantial revenue from drugs sold in the State of New York, and/or should reasonably expect the acts described in this complaint to have consequences in the State of New York.

18. Venue is appropriate in this District under 15 U.S.C. § 22 because Defendants each transact business in this district and may be found in this district. Venue is also appropriate in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this district; and, in the alternative, venue is appropriate in this District under 28 U.S.C. § 1391 because Defendants are not all residents of the same State and are subject to this Court's personal jurisdiction.

ALLEGATIONS

I. Drug companies have long offered Contract Pharmacy 340B Drug Discounts to eligible hospitals and clinics.

A. The 340B Drug Discount is a longstanding discount offered by drug companies to hospitals and clinics serving underserved populations.

19. Prior to Defendants' conspiracy, all drug companies participating in Medicaid and Medicare Part B had offered Contract Pharmacy 340B Drug Discounts as part of their participation in the 340B Drug Discount Program.

20. The 340B Drug Discount Program dictates the calculation of the 340B Drug Discount. The 340B Drug Discount is provided by the manufacturer to the covered entities participating in the 340B Drug Discount Program. That program provides the infrastructure for drug companies to offer the 340B Drug Discount through contract pharmacies. And, until the second half of 2020, all drug companies participating in Medicaid and Medicare Part B had offered the Contract Pharmacy 340B Drug Discount.

1. The 340B Drug Discount Program supports healthcare programs for the underserved.

21. The 340B Drug Discount Program was created in 1992 by Section 340B of the Public Health Service Act, 42 U.S.C. § 256b (Section 340B), to require discounts on outpatient drugs purchased by healthcare providers serving underserved populations. "Under § 340B," "manufacturers participating in Medicaid must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 115 (2011).

22. The program ensures that certain safety-net hospitals and clinics, deemed "covered entities" under the statute, have access to discounts when purchasing outpatient drugs. 42 U.S.C. § 256b(a)(4). As defined by Section 340B, covered entities include a number of health clinics, such as: federally qualified health centers; federally qualified health center look-alikes; native Hawaiian health centers; tribal or urban Indian health centers; Ryan White HIV/AIDS clinics; black lung clinics; comprehensive hemophilia diagnostic treatment centers; Title X family planning projects; sexually transmitted disease clinics; and tuberculosis clinics. *See* 42 U.S.C. § 256b(a)(4). In addition, and as likewise defined by Section 340B, covered entities include hospitals meeting certain statutory criteria, such as: children's hospitals; critical access hospitals; free standing cancer hospitals; sole community hospitals; rural referral centers; and disproportionate share hospitals. *See* 42 U.S.C. § 256b(a)(4).

23. The purpose of the 340B Drug Discount Program is "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 120-384(II), at 12 (1992). Covered entities with access to 340B Drug Discounts can do so in various ways. For one, a covered entity can save money when paying the ceiling price for a covered outpatient drug needed for an

uninsured or an underinsured patient; there, 340B Drug Discounts represent an expense savings for unreimbursed care. Moreover, for patients with insurance, a covered entity can net revenue from the spread between the drug's price—lowered by the 340B Drug Discount—and any reimbursement above that price. The net savings and revenue generated through access to 340B Drug Discounts is sometimes referred to as 340B Savings.

24. 340B Savings are often a critical component of covered entities' ability to provide healthcare services to patients. For some covered entities, including federally qualified health centers, 340B Savings directly subsidize the covered entities' efforts to make drugs affordable to patients at lower costs. For other covered entities, including many hospital participants, 340B Savings helps them fund and expand critical services for the most vulnerable patients, such as addiction and mental health services, and charity care, among other things.

25. 340B Savings are critical to the named Plaintiffs. For example, Mosaic Health's 340B Savings help fund sliding fee discounted medications for patients in need.

26. The clinics that are 340B covered entities predominantly serve low-income or underserved patient populations. For instance, federally qualified health centers are community-based health care providers that receive funds from HHS to provide primary care and other services in underserved areas. They must meet a stringent set of requirements, including providing care on a sliding-fee scale based on patients' ability to pay. Moreover, under federal grant requirements, federally qualified health centers must use any 340B Savings in furtherance of their healthcare safety-net mission. *See* 42 U.S.C. § 254b(e)(5)(A), (D).

27. The hospitals that are 340B covered entities bear disproportionate burdens in serving low-income and underserved patient populations. For instance, disproportionate share hospitals are, by definition, hospitals that serve a significantly disproportionate number of low-

income patients. Moreover, to be a covered entity for the 340B Drug Discount Program, a private hospital that meets the disproportionate share hospital definition must also be a nonprofit and must agree to provide charity care. *See* 42 U.S.C. § 256b(a)(4)(L).

28. Section 340B directs the Secretary of the Department of Health and Human Services (HHS) to enter into an agreement with every drug manufacturer participating in State Medicaid programs and Medicare Part B. 42 U.S.C. § 256b(a); *see also* 42 C.F.R. § 10.2. These agreements are known as pharmaceutical pricing agreements (PPAs). Every drug manufacturer participating in Medicaid or Medicare Part B enters into a PPA and offers 340B Drug Discounts. Drug companies that refuse to sign a PPA cannot participate in Medicaid and Medicare Part B. More than 1,000 drug companies have signed PPAs with HHS, including each of the Defendants and all of the other top 250 drug companies.[1]

2. Since 1992, the 340B Drug Discount has been calculated in the same manner.

29. Since its inception, the 340B Drug Discount has been a defined discount, specific to each drug, calculated by the 340B Drug Discount Program.

30. Section 340B and PPAs dictate the methodology for calculating 340B Drug Discounts. Section 340B creates the discount by imposing a ceiling price. *See* 42 U.S.C. § 256b(a)(1); *see also* 42 C.F.R. § 10.10. The ceiling price for a drug is generally equal to the "Average Manufacturer Price" minus a "Unit Rebate Amount." 42 C.F.R. § 10.10(a). The extent to which the ceiling price reduces the available price for drugs is known as the 340B Drug Discount. 340B Drug discounts often provide savings of 20% to 50%.

[1] *See, e.g.*, Torreya Capital LLC, "The Pharma 1000: Top Global Pharmaceutical Company Report" (Sept. 2020).

31. Drug companies must report their 340B ceiling prices on a quarterly basis. *See* 42 U.S.C. § 256b(a)(1). Those reports must be made to the Health Resources and Services Administration (HRSA), the HHS agency that administers the 340B Drug Discount Program. HRSA makes ceiling prices available to covered entities through its 340B Office of Pharmacy Affairs Information System (340B OPAIS), an online database that allows covered entities to access ceiling prices for covered outpatient drugs.

32. The 340B Drug Discount is thus a defined discount, calculated by statutory rules, and verifiable through 340B OPAIS.

3. Drug companies offer 340B Drug Discounts directly to covered hospitals and clinics.

33. Under Section 340B and PPAs, drug companies—not drug distributors—are responsible for offering covered entities the 340B Drug Discount.

34. This is clear from the statute, which states that each PPA "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase" at a price including the 340B Drug Discount. 24 U.S.C. § 256b(a)(1).

35. Defendants themselves have acknowledged that the obligation to provide 340B Drug Discounts to covered entities is theirs alone. As Sanofi has explained, "Section 340B . . . requires drug manufacturers participating in the 340B Program to offer certain drugs at a significant discount to a list of entities (known as 'covered entities') defined by statute." *See* Complaint ¶ 23, *Sanofi-Aventis U.S., LLC v. Azar*, 21-cv-634 (D.N.J. filed Jan. 12, 2021). Similarly, Eli Lilly has stated, "Under the 340B Statute, pharmaceutical manufacturers 'must' offer steep discounts on their products to certain 'covered entities.'" *See* Complaint, *Eli Lilly and Company v. Azar*, 21-cv-81 (S.D. Ind. filed Jan. 12, 2021). For its part, Novo Nordisk has spelled out that "Section 340B of the Public Health Service Act requires pharmaceutical

manufacturers to offer their outpatient drugs at deeply discounted prices to an enumerated list of 'covered entities' for the purpose of ensuring that vulnerable and low-income patients have better access to prescription medications." *See* Complaint ¶ 2, *Novo Nordisk Inc. v. Azar*, 3:21-cv-806 (D.N.J. filed Jan. 15, 2021). So too, AstraZeneca has acknowledged "its statutory obligations . . . to offer 340B drugs to each covered entity on non-discriminatory terms at the 340B price." *See* Complaint ¶ 3, *AstraZeneca Pharmaceuticals LP v. Azar*, 1:21-cv-27 (D. Del. filed Jan. 12, 2021). As AstraZeneca has further detailed, the 340B Program requires that each "manufacturer must 'offer each covered entity covered outpatient drugs for purchase' at a specified [340B] discount price . . . This is known as Section 340B's 'must-offer' requirement." *Id.* ¶ 20.

36. Consequently, as a matter of law and practice, 340B Drug Discounts are offered by, funded by, and provided by drug companies to covered entities.

4. Oftentimes, drug companies contract with drug distributors to convey 340B Drug Discounts to covered entities.

37. Oftentimes, drug companies rely on distributors and suppliers, such as Cardinal Health, Inc., and McKesson Corporation, to arrange for drug purchasing with covered entities.

38. But those arrangements do not change the nature of the 340B Drug Discount. That discount remains a discount offered and provided by drug companies to covered entities. Indeed, as noted above, drug companies are obligated to provide 340B Drug Discounts to covered entities themselves.

39. As the Federal rules state, "Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer." *See* 42 C.F.R. § 10.11(b)(2); *see also* Final Rule, 82 Fed. Reg. 1220, 1224 ("Manufacturers are ultimately responsible for ensuring a covered entity receives a drug at or below the 340B ceiling

price" and "have control over the distribution of covered outpatient drugs, including those distributed by wholesalers, distributers, and agents.").

40. Drug companies ensure that they are offering and providing 340B Drug Discounts to covered entities, even when a distributor serves as an intermediary, by various arrangements. Most commonly, the drug company instructs the distributor to provide the 340B Drug Discount for the sale of any covered outpatient drugs to covered entities. The distributor includes that discount, at the instruction of the drug company, and reports the discounts back to the drug company. The drug company then funds the discount, oftentimes by paying a distributor's invoice for the 340B Drug Discount amount provided (a procedure sometimes called a chargeback). Distributors have no ability to keep any of the 340B Drug Discount. Rather, all of the 340B Drug Discount is conveyed from the drug company to the covered entity.

41. In this way and others, drug distributors do no more than convey 340B Drug Discounts from drug companies to covered entities. Drug distributors themselves have no access to 340B Drug Discounts.

42. Consequently, even when drug distributors serve as intermediaries, the 340B Drug Discount is offered and provided from the drug companies to the covered entities.

B. For a decade, drug companies have universally offered hospitals and clinics access to 340B Drug Discounts at Contract Pharmacies (*i.e.*, Contract Pharmacy 340B Drug Discounts).

1. At the inception of the 340B Program, many clinics struggled to obtain meaningful benefits from the 340B Program.

43. Following the enactment of the 340B Program in 1992 and "[d]uring the early period of program implementation, it became apparent that only a very small number of the [then] 11,500 covered entities used in-house pharmacies (approximately 500)." Final Notice, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). Moreover, "many of the larger groups of covered

entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend[ed] upon outside pharmacy services." *Id.* Yet, "the delivery of pharmacy services [wa]s central to the mission" of these covered entities "and a legal mandate in some instances." *Id.*

44. As HHS has noted, this gap was "not surprising" because "the Program is aimed at benefiting providers" that can be some combination of "small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations." *See* U.S. Dep't of Health & Human Servs. Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 4 (Dec. 30, 2020). Some of these "are the poster children of providers that one would expect to lack an in-house pharmacy." *Id.*

45. Because of this gap, covered entities sought regulatory assistance in promoting access to 340B Drug Discounts through Contract Pharmacies. And "[a]s early as 1993, several covered entity groups . . . came forward to assist [HHS] in developing a workable mechanism to use outside pharmacies." *Id.*

46. HHS recognized the problem this gap presented. As it explained, "if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program," "they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." Final Notice, 61 Fed. Reg. 43,550 (Aug. 23, 1996).

2. In 1996 and again in 2010, HHS published guidelines for drug companies to offer Contract Pharmacy 340B Drug Discounts.

47. In order to expand access to 340B Drug Discounts, in 1996 and 2010, HHS set out guidelines for access to 340B Drug Discounts at Contract Pharmacies.

48. In 1996, HHS issued a final notice with guidelines for drug companies and covered entities to use in setting up Contract Pharmacy arrangements, so that covered entities could access 340B Drug Discounts at Contract Pharmacies. Final Notice, 61 Fed. Reg. 43,549 (Aug. 23, 1996). HHS articulated its position "that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating [340B] manufacturer, the statute directs the manufacturer to sell the drug at the [340B] discounted price." *Id.* at 43,549. When "the entity directs the drug shipment to its contract pharmacy, [there is] no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance." *Id.* at 43,549-550.

49. The 1996 final notice provided basic guidelines for implementing Contract Pharmacies to access 340B Drug Discounts. The guidelines encouraged written agreements between the covered entity and the Contract Pharmacy. *See id*. at 43,555. Under the guidelines, the covered entity would purchase the drug, but a "'ship to, bill to' procedure may be used in which the covered entity purchases the drug [and] the manufacturer bills the entity for the drug that it purchased, but [the manufacturer] ships the drug directly to the contract pharmacy." *Id.* The notice included guidelines for limiting the purchase of 340B Drug Discounts to drugs purchased for eligible patients of the covered entity. *See id*.

50. In 2010, HHS issued another final notice with additional guidelines for the use of Contract Pharmacies to access Contract Pharmacy 340B Drug Discounts. *See* Final Notice, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

51. The 2010 final notice included guidelines for the use of "multiple contract pharmacy arrangements," greenlighting the use of multiple retail pharmacies as Contract Pharmacies for a covered entity. *See id*. at 10,273.

52. HRSA's Office of Pharmacy Affairs has facilitated the use of Contract Pharmacies through its 340B OPAIS. In accordance with HHS instructions, covered entities register the names and locations of their Contract Pharmacies in the 340B OPAIS database. Drug companies can access that same database to verify that a particular pharmacy is serving as a Contract Pharmacy for a particular 340B covered entity before making 340B Drug Discounts available to a covered entity purchasing drugs for shipment to that pharmacy location.

53. The expansion of Contract Pharmacies has provided real benefits for patients, including by expanding patient access and choice. For instance, prior to the expansion, patients of federally qualified health centers were typically able to receive subsidized drugs (on a sliding-fee scale) at a single pharmacy, which might have been far from the health center's patients' homes or otherwise inconvenient. After the expansion, however, patients of federally qualified health centers now typically have a wide range of choices and are able to use a wide variety of Contract Pharmacies. Thus, for example, whereas Mosaic Health patients previously had a single pharmacy location to obtain sliding-fee scale drugs, they can now visit over a dozen different locations.

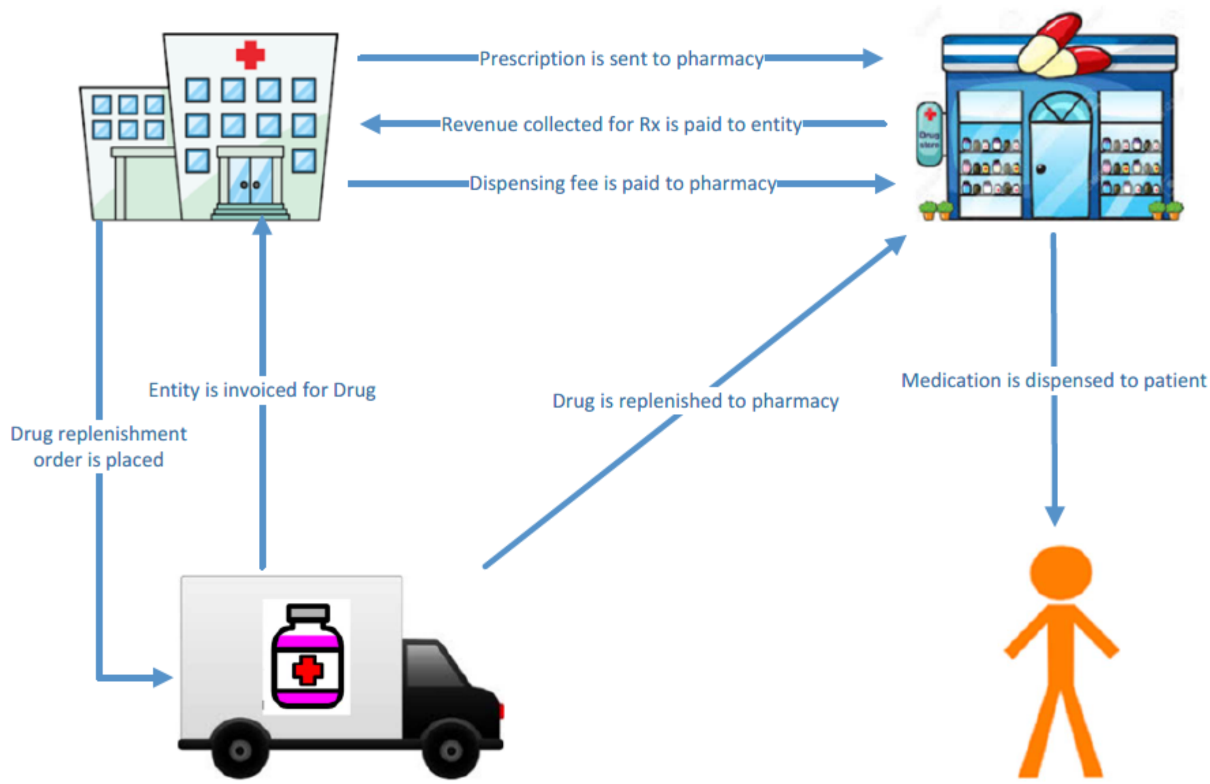
54. The expansion of Contract Pharmacies has also benefitted patients by expanding the range of covered entities' healthcare services available and by allowing covered entities to fund additional charity care. For instance, 340B Savings have supported hospitals' abilities to provide substantial uncompensated and charity care, including for unreimbursed care for cancer patients, unreimbursed care for substance abuse treatment, subsidizing losses for pediatric care, and supporting community health programs. Those efforts have expanded the breadth and quality of healthcare services available to patients and have reduced the costs of those services, including drugs, to the neediest.

3. After that, drug companies participating in the 340B Drug Discount Program universally offered Contract Pharmacy 340B Drug Discounts.

55. Since at least 1996, and in greater volumes since 2010, all drug companies participating in the 340B Drug Discount Program have offered Contract Pharmacy 340B Drug Discounts to covered entities. To do so, drug companies have offered covered entities the 340B Drug Discount on covered outpatient drugs purchased on the covered entities' own accounts but shipped to their registered Contract Pharmacy sites.

56. Oftentimes, this is accomplished through arrangements among covered entities, Contract Pharmacies, distributors, and so-called 340B vendors. A typical arrangement is as follows: A covered entity's patient arrives at a Contract Pharmacy (*e.g.*, a RiteAid) for a covered outpatient drug; the pharmacy fills the patient's prescription. The pharmacy, sometimes itself and sometimes working with a 340B vendor (*e.g.*, CaptureRx) running matching algorithms, reviews the pharmacy prescription to identify the patient's prescription as 340B eligible and to match it to a particular covered entity. If it is so matched, the pharmacy fills the prescription with inventory from the purchasing account of that covered entity—the account by which the covered entity purchases covered outpatient drugs and obtains Contract Pharmacy 340B Drug Discounts from drug companies. The pharmacy then charges the patient for any required co-pay or, if the patient is uninsured, any required fee, adjusted downward as appropriate by any sliding-fee scale arrangement between the pharmacy and the covered entity (as is often the case with federally qualified health centers). To the extent the patient has insurance coverage from third-parties, such as private insurers or Medicare Part D, the pharmacy collects those reimbursements for the covered entity's account. The pharmacy then remits any amounts collected—whether from the patient or from a third party—to the covered entity, and the covered entity pays the pharmacy a dispensing fee.

57. The arrangements described above can be visualized as follows:



58. Contract pharmacy arrangements have thus allowed covered entities to obtain Contract Pharmacy 340B Drug Discounts and, consequently, to generate 340B Savings. These arrangements have been the status quo for a decade.

59. For a decade, all pharmaceutical companies participating in Medicaid and Medicare Part B have offered Contract Pharmacy 340B Drug Discounts to covered entities. This has been the universal practice of all drug companies participating in the 340B Program until the recent events (by just a few companies) described in this Complaint.

60. The most recent data published by HHS in June 2021 reflects that more than 4,000 covered entities have Contract Pharmacy arrangements to obtain Contract Pharmacy 340B Drug Discounts.

61. Even now, with the significant exception of Defendants, every one of the 1,000-plus drug companies participating in the 340B Program—and every one of the top 250 drug companies, apart from Defendants—continues to offer Contract Pharmacy 340B Drug Discounts.

62. Defendants' recent actions are the exceptions that prove the rule.

C. Any drug company that, acting alone, restricted Contract Pharmacy 340B Drug Discounts could seriously jeopardize its market share over months or years.

63. Any drug company that restricted the availability of Contract Pharmacy 340B Drug Discounts would put its market share at risk.

64. Hospitals and clinics can and do prefer certain drugs over others. Where drugs are clinically equivalent or therapeutically interchangeable, hospitals and clinics will consider other factors. Those factors can include the cost of the drugs to the patient or hospital/clinic, or the ability of the drug to provide revenue to the hospital/clinic. Typically, a drug with a Contract Pharmacy 340B Drug Discount would be preferred to a clinically equivalent and therapeutically interchangeable drug without a Contract Pharmacy 340B Drug Discount.

65. Hospitals and clinics can steer patients towards preferred drugs in various ways. For instance, a hospital or clinic can decide to stock its inventory with one of a series of clinically equivalent or therapeutically interchangeable drugs. If that drug were successfully administered during an outpatient visit, it would more likely be prescribed. As another example, a prescribing physician at a hospital or clinic could choose to start new patients on a particular medicine among a series of clinically equivalent or therapeutically interchangeable drugs. Through these and other actions, hospitals and clinics can influence which drug, out of a series of clinically equivalent or therapeutically interchangeable drugs, is prescribed for their patients.

66. Significantly, however, most efforts to steer patients towards a particular drug, among a series of clinically equivalent or therapeutically interchangeable drugs, require months

or years to complete. The efforts are most successful with new patients, who may receive an administered drug for the first time during an outpatient visit or may receive a prescription for a particular type of drug (*e.g.*, an incretin mimetic) for the first time. New patients arrive gradually, which takes time. As for existing patients, any efforts to convert their usage from one drug to another within a series of clinically equivalent or therapeutically interchangeable drugs is typically a slower process.

67. Consequently, the market share of a drug company that limited Contract Pharmacy 340B Drug Discounts would eventually be threatened by competitors that continued to offer clinically equivalent and therapeutically interchangeable drugs to covered entities with Contract Pharmacy 340B Drug Discounts. That threat, however, would require many months to materialize.

II. Defendant drug companies—the same companies that recently limited Contract Pharmacy 340B Drug Discounts—sell competing diabetes medicines, among other competing products.

68. Defendants dominate three of today's most lucrative markets for diabetes treatments: (i) rapid-acting analog insulins; (ii) long-acting analog insulins; and (iii) incretin mimetics. Defendants compete against each other, as horizontal competitors, in these markets.

69. Diabetes occurs when a person has too much glucose (a type of sugar) in their blood stream. Insulin is involved in the pathway that permits glucose to leave the bloodstream and enter cells. With insufficient insulin, glucose remains at high levels in the blood, leading to high blood sugar levels.

70. There are two types of diabetes. Type 1 diabetes, which is usually diagnosed in children and young adults, is a condition in which the body does not produce any insulin. Type 2 diabetes, which is the more common form, is a condition in which the body either produces insufficient insulin or where cells become resistant to insulin to a certain degree. All patients

with Type 1 diabetes require insulin treatments; and about a quarter of patients with Type 2 diabetes require insulin treatments.

71. Diabetes is a widespread disease in the United States. Over 30 million people, making up nearly ten percent of the Nation's population, live with diabetes. It is a life-threatening disease that, for many, requires daily treatments to survive. Absent treatment, diabetes can cause serious harm and organ damage. Moreover, untreated diabetes can lead to diabetic ketoacidosis, which can be fatal. Indeed, according to the Centers for Disease Control and Prevention, diabetes was the seventh leading cause of death in 2019.

72. Diabetes is often coincident with low-income populations and in lower-income neighborhoods that are underserved by private healthcare practices. *See, e.g.*, Gaskin, et al., "Disparities in Diabetes: The Nexus of Race, Poverty, and Place," 104 Am. J. Public Health 2147 (Nov. 2014).

73. Diabetes is likewise a common area of treatment for 340B covered entity hospitals and clinics. According to HRSA, one in seven federally qualified health center patients has diabetes and nearly one in three of those has uncontrolled diabetes.

74. Consequently, diabetes medications make up a significant portion of 340B covered entities' outpatient prescriptions and 340B Drug Discounts. And three of the most significant diabetes medications are rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

A. Sanofi, Eli Lilly, and Novo Nordisk compete in the sale of rapid-acting analog insulins.

75. Analog insulins are a type of human insulin. They are an important treatment for diabetes. Indeed, clinicians often prefer analog insulins to other forms of insulin, and the

American Diabetes Association recommends analog insulins for the treatment of individuals with both type 1 diabetes and type 2 diabetes.

76. There are both rapid-acting analog insulins and long-acting analog insulins.

77. Sanofi, Eli Lilly, and Novo Nordisk all produce and sell rapid-acting analog insulins. Eli Lilly developed Humalog, the first analog (meaning, man-made) insulin in the mid-1990s; it is a rapid-acting analog insulin that can be rapidly absorbed. Novo Nordisk then developed its own rapid-acting analog insulin, Novolog, around 2000. And, in 2018, Sanofi launched a follow-on insulin product, Admelog, based on Eli Lilly's Humalog.

78. Since 2019, Eli Lilly has sold Humalog both under the brand name Humalog and as an authorized generic called insulin lispro. Since January 2020, Novo Nordisk has sold Novolog both under the brand name Novolog and as an authorized generic called insulin aspart.

79. Sanofi, Eli Lilly, and Novo Nordisk currently manufacture and sell the following rapid-acting analog insulins, which are clinically equivalent and therapeutically interchangeable, with each drug capturing the approximate market share listed,[2] as of July 2020:

	Name	**Company**	**Approximate Market Share**
Rapid-Acting Analog Insulins	Apidra	Sanofi	6%
	Admelog	Sanofi	5%
	Humalog/Insulin Lispro	Eli Lilly	44%
	Fiasp	Novo Nordisk	1%
	Novolog/Insulin Aspart	Novo Nordisk	44%

80. Eli Lilly also sells biosimilar versions of Humalog. On June 15, 2020, the FDA approved another Eli Lilly rapid-acting analog insulin, Lyumjev. Eli Lilly began selling Lyumjev in the United States on or about October 7, 2020.

[2] *See, e.g.*, Bob Herman, "Insulin net sales over time by company and brand," Axios (Feb. 13, 2020), *at* https://docs.google.com/spreadsheets/d/1PTpcErbuWvUEMhIQpGs0-KnQBdhGgUP4kjygyU1j9b8/edit#gid=0 (based on 2019 sales).

81. In addition to rapid-acting analog insulins, there are rapid-acting recombinant human insulins. Those insulins are Humulin R, sold by Eli Lilly, and Novolin R, sold by Novo Nordisk.

B. Sanofi, Eli Lilly, and Novo Nordisk compete in the sale of long-acting analog insulins.

82. Another class of insulin are long-acting analog insulins. The American Diabetes Association has described long-acting analog insulin as the "most convenient initial insulin regimen." Am. Diabetes Ass'n, *Approaches to Glycemic Care*, 38 Diabetes Care S52, S57 (2016).

83. Sanofi, Eli Lilly, and Novo Nordisk all produce and sell long-acting analog insulins. Around 2000, Sanofi introduced the first long-acting analog insulin, Lantus. Then, Novo Nordisk introduced its own long-acting analog insulin, Levemir. Those drugs were followed by Toujeo, Sanofi's higher-dose long-acting analog insulin; Tresiba, another long-acting analog insulin from Novo Nordisk; and Basaglar, Eli Lilly's long-acting analog insulin.

84. Sanofi, Eli Lilly, and Novo Nordisk currently manufacture and sell the following long-acting analog insulins, which are clinically equivalent and therapeutically interchangeable, with each drug capturing the approximate market share listed,[3] as of July 2020:

[3] *See, e.g.*, Bob Herman, "Insulin net sales over time by company and brand," Axios (Feb. 13, 2020), *at* https://docs.google.com/spreadsheets/d/1PTpcErbuWvUEMhIQpGs0-KnQBdhGgUP4kjygyU1j9b8/edit#gid=0 (based on 2019 sales).

	Name	Company	Approximate
Long-Acting Analog Insulins	Lantus	Sanofi	42%
	Toujeo	Sanofi	12%
	Basaglar	Eli Lilly	13%
	Levemir	Novo Nordisk	17%
	Tresiba	Novo Nordisk	17%

C. Sanofi, Eli Lilly, Novo Nordisk and AstraZeneca compete in the sale of incretin mimetics.

85. Another class of diabetes medications, apart from insulins, is the class of incretin mimetics called glucagon-like peptide 1 agonists (GLP-1). These drugs work by increasing the level of hormones called incretins. Incretins help the body produce more insulin and can reduce the amount of excess glucose being produced by the liver.

86. Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca all produce and sell incretin mimetics. Eli Lilly developed the first incretin mimetic, Byetta (now sold by AstraZeneca), from the saliva of a lizard, the gila monster, and introduced it in 2005. Since then, the FDA has approved incretin mimetics by Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca.

87. Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca currently manufacture and sell the following incretin mimetics, which are clinically equivalent and therapeutically interchangeable, with each drug capturing the approximate market share listed,[4] as of July 2020:

[4] *See, e.g.*, Bashar Issa, "Things to Consider Before Buying Eli Lilly's Shares," (May 27, 2021), *at* https://seekingalpha.com/article/4431676-things-to-consider-before-buying-eli-lillys-shares (based on year-end 2020 sales data).

	Name	Company	Approximate Market Share
Incretin mimetics	Adlyxin	Sanofi	1%
	Trulicity	Eli Lilly	40%
	Victoza	Novo Nordisk	24%
	Ozempic	Novo Nordisk	28%
	Rybelsus	Novo Nordisk	2%
	Bydureon	AstraZeneca	4%
	Byetta	AstraZeneca	1%

D. In addition, Sanofi, Eli Lilly, Novo Nordisk and AstraZeneca compete in the sale of other drugs.

88. Defendants manufacture and sell other competing drugs, as well.

89. For instance, Eli Lilly and AstraZeneca both produce competing antipsychotic medications to treat bipolar disorder and schizophrenia. Eli Lilly produces the drug Zyprexa, and AstraZeneca produces the drug Seroquel.

90. But such drugs, along with Defendants' other competing drugs, make up relatively small fractions of Defendants' collective sales of covered outpatient drugs in the 340B Drug Discount Program, compared to their collective sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

E. Defendants report billions of dollars in annual U.S. sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

91. Within the United States, Defendants annually sell billions of dollars of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics. For each Defendant, these diabetes medications contribute significantly to the company's financial performance, representing hundreds of millions or billions of dollars in annual sales for each company.

92. At Eli Lilly, for instance, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are the most significant drugs in the company's portfolio. Trulicity, its incretin mimetic, generated more than twice as much revenue as any other Eli Lilly product in

2020, with U.S. revenues of $3.8 billion. *See* Eli Lilly Annual Report (2020) at 46. Eli Lilly's second highest revenue generating drugs are its rapid-acting analog insulins, Humalog and Insulin Lispro, which generated U.S. revenue of $1.5 billion. *See id.* Eli Lilly's long-acting analog insulin drug, Basaglar, was also among its highest revenue producing drugs, generating revenue of $842.3 million in the U.S. Together, Eli Lilly's rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics account for $6.2 billion, or nearly 45%, of its 2020 U.S. revenue.

93. These drugs are also a significant part of Eli Lilly's strategy for growth. Eli Lilly announced that its 2020 revenue growth "was driven by increased volume primarily for" a handful of drugs, including Trulicity, *id.* at 45, which had grown by 23% year-over-year, and that Eli Lilly's future "[r]evenue growth is expected to be driven by volume from Trulicity," first among a list of other drugs. *Id.* at 55.

94. At Novo Nordisk, too, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are the most significant drugs in the company's portfolio. Together, Novo Nordisk's rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics accounted for approximately $7.3 billion (converted from a reported $44.3 billion DKKs), or 77%, of its 2020 U.S. revenue. *See* Novo Nordisk Annual Report (2020) at 54.

95. These drugs are part of Novo Nordisk's business strategy, as well. Novo Nordisk describes its business, first and foremost, as "a world leader in Diabetes care," with "one of the broadest diabetes product portfolios in the industry, including new generation insulin, a full portfolio of modern insulin and human insulin as well as a portfolio of GLP-1 receptor agonists [incretin mimetics]." *See* Novo Nordisk Form 20-F (2020) at 5. Novo Nordisk explains that "[d]ue to the increasing number of people with diabetes, the global pharmaceutical market for

treatment of diabetes continues to grow." *Id.*at 6. It claims to have "maintained a leading position in the overall diabetes care market" in the United States, among "downward pressure on manufacturers' net prices." *Id.* at 6. It acknowledges that "[i]n the global insulin market, Novo Nordisk, Eli Lilly and Sanofi are the most significant companies measured by market share." *Id.* at 6. As to the incretin mimetics market, Novo Nordisk claims that "the use of glucagon-like peptide-1 (GLP-1) [incretin mimetics] as a treatment option for people with Type 2 diabetes has continued to increase resulting in significant growth of the GLP-1 market." *Id.* at 6. It acknowledges that, in the incretin mimetics market, as in the insulin market, "Novo Nordisk, Eli Lilly and Astra Zeneca are the most significant companies . . . [as] measured by market share," and that, as to incretin mimetics, "Novo Nordisk is the global market leader . . . with a 50% volume market share as of December 31, 2020." *Id.* at 6. Novo Nordisk reported that 2020 sales of diabetes medications increased by 5%, "driven by GLP-1 [incretin mimetics] growth." Novo Nordisk Annual Report (2020) at 29.

96. At Sanofi, rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics make up a significant portion of the company's business and are a defining feature of the company's history. Together, Sanofi's rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics accounted for approximately $1.7 billion (converted from a reported $1.4 billion Euros) in 2020 U.S. revenue. *See* Sanofi Form 20-F (2020) at 64.

97. Incretin mimetics are a substantial part of AstraZeneca's business, as well as an area targeted for growth. AstraZeneca reported U.S. sales of $382 million for Bydureon in 2020 and $37 million for Byetta. *See* AstraZeneca Annual Report (2020) at 187. Moreover, the company's 2020 annual report highlighted that diabetes is the company's largest therapy area

world market, at an estimated size of $99.6 billion, or approximately a full half of the overall therapy markets targeted by the company. *See id.* at 36.

F. Defendants' sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are extremely significant at Contract Pharmacies.

98. Among the various drugs sold by Defendants, sales of their rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are particularly significant among sales at Contract Pharmacies serving covered entities' patients.

99. Upon information and belief, the overwhelming majority of Contract Pharmacy 340B Drug Discounts for drugs sold by Defendants at Contract Pharmacies are attributable to their rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics. Upon information and belief, approximately 80% of covered entities' 340B Savings from Defendants are attributable to Defendants' rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics, whereas all of Defendants' other drugs account for only 20% of 340B Savings at Contract Pharmacies.

III. In the middle of 2020, Defendants made strident lobbying efforts that failed to limit 340B Drug Discounts for diabetes medicines.

100. Defendants' price-fixing conspiracy began as soon as their collective lobbying efforts failed. Through mid-summer, Defendants had spent millions collectively lobbying the federal government (in efforts not challenged here) to limit 340B Drug Discounts with respect to diabetes medicines. Defendants, as part of long-running lobbying by drug companies, had sought to limit the level of hospital participation in the 340B Program, limit which patients could qualify for 340B Drug Discounts, require that all discounts be passed through to patients, and limit the availability of Contract Pharmacy 340B Drug Discounts. But Defendants' lobbying efforts failed. That failure became evident with the issuance of Executive Order 13937, which did little to limit Contract Pharmacy 340B Drug Discounts. As soon as it became clear that

Defendants' collective lobbying efforts had failed, Defendants turned to another plan focused on just one of their goals—collusively eliminating or otherwise limiting Contract Pharmacy 340B Drug Discounts for their drugs, which dominate the rapid-acting analog insulin, long-acting analog insulin, and incretin mimetic markets of diabetes medications.

A. The President's July 24th executive order addressing the use of 340B Drug Discounts for insulin promised to have little impact.

101. On July 24, 2020, then-President Donald Trump issued Executive Order 13937, entitled, "Access to Affordable Life-Saving Medications." *See* 85 Fed. Reg. 45,755 (July 29, 2020). The executive order addressed the use of insulin (as well as epinephrine) within the 340B Drug Discount Program. The order noted that "[i]nsulin is a critical and life-saving medication that approximately 8 million Americans rely on to manage diabetes," and that "[t]he price of insulin in the United States has risen dramatically over the past decade." *Id.* The order further noted that "many Americans still struggle to purchase these products." *Id.*

102. The executive order noted that the 340B Drug Discount lowers the price of insulin for covered entities. As the order recited, while "[t]he list price for a single vial of insulin today is often more than $250," "many of these products" may be purchased under the 340B Program "at a price of one penny per unit of measure." *Id.* The order then stated, with significant qualification, that "[t]hese steep discounts, however, are not *always* passed through to low-income Americans at the point of sale." The executive order was aimed at addressing that issue.

103. But the executive order was extremely limited in scope. In particular, it applied only to federally qualified health centers. The President ordered only that HHS should "take action to ensure future grants . . . are conditioned upon [federally qualified health centers] having established practices to make insulin . . . available at the discounted price paid by the [federally qualified health center] grantee or sub-grantee under the 340B Prescription Drug Program (plus a

minimal administration fee) to individuals with low incomes, . . . who: (a) have a high cost sharing requirement for . . . insulin; (b) have a high unmet deductible; or (c) have no health care insurance." *Id.*

104. Executive Order 13937 promised to have relatively little impact on the volume of 340B Drug Discounts for insulin medications for several reasons.

105. *First*, because the order was limited to federally qualified health centers, it would have no impact on any of the other categories of covered entities. The order did not apply to any of the other nine categories of clinics that can be covered entities. Nor did it apply to any hospital covered entities.

106. *Second*, the order appeared to impose largely redundant legal requirements. Federally qualified health centers are funded through Section 330 of the Public Health Services Act, 42 U.S.C. § 254b. Under that authority, HHS "may make grants for the costs of the operation of public and nonprofit private health centers that provide health services to medically underserved populations." 42 U.S.C. § 254b(e)(1)(A). For a health center to obtain such funding, it must provide "the required primary health services" set out in the statute. 42 U.S.C. § 254b(k)(3)(A). And those "required primary health services," by definition, include the provision of "pharmaceutical services." 42 U.S.C. § 254b(b)(1)(A)(i)(V). Moreover, under HRSA's Health Center Compliance Manual, health centers "must operate in a manner such that no patient shall be denied service due to an individual's inability to pay," and are already obligated to provide a "full discount to individuals and families with annual incomes at or below [the poverty line]." So, it was unclear what real effects the executive order might have in changing patient prices for insulin.

107. *Third*, and relatedly, the executive order did not appear to impact sales of insulin medication to federally qualified health centers in the 340B Program. As noted, federally qualified health centers must ensure their patients have access to drugs. Those centers would seek to do so at the best price. Requiring federally qualified health centers to pass all 340B Savings onto patients would not change the health centers' incentives—they would still seek to purchase the same volume of drugs, with Contract Pharmacy 340B Drug Discounts included. So, as long as federally qualified health centers purchased the same volume of drugs and, as per the executive order, continued to do so with Contract Pharmacy 340B Drug Discounts, insulin-manufacturers' profit margins would be unaffected.

B. The executive order followed Defendants' apparently unsuccessful but coordinated lobbying efforts to limit 340B Drug Discounts for diabetes medication.

108. Upon information and belief, Defendants worked together to lobby the Federal Government, including HHS and White House, to obtain legal or agency guidance changes to limit 340B Drug Discounts, particularly for diabetes medicines like analog insulin and incretin mimetics. This allegation is supported by Defendants' lobbying records.

109. In the reporting periods that encompassed lobbying in advance of the President's executive order (*i.e.*, April 1 through June 30, and July 1 through September 30), Defendants spent significant resources lobbying the Federal Government. According to their public disclosures, each Defendant in that period lobbied the Federal Government regarding the 340B Program: Sanofi spent upwards of $320,000 on external lobbyists and upwards of $1.9 million of its own resources on that effort; Eli Lilly spent upwards of $290,000 on external lobbyists and upwards of $3.18 million of its own resources; Novo Nordisk spent upwards of $250,000 on external lobbyists and upwards of $90,000 of its own resources; and AstraZeneca spent upwards of $240,000 on external lobbyists and upwards of $1.23 million of its own resources on that

effort. In total then, Defendants report spending upwards of $1.1 million on external lobbyists and upwards of $6.4 million of their own resources lobbying 340B Drug Discounts in this short period.

110. Not only were Defendants lobbying the Federal Government as to 340B Drug Discounts, but they were also lobbying regarding insulin and other diabetes medication issues. The three Defendants dominating the analog insulin markets—Sanofi, Eli Lilly, and Novo Nordisk—all report lobbying insulin issues alongside 340B Drug Discount issues. And both Novo Nordisk and AstraZeneca report lobbying diabetes issues at the same time.

111. Defendants were coordinated in their lobbying during this time period, both in terms of issues as set out above and in terms of lobbyists. They used common lobbyists. For instance, all four Defendants report that, in this period, they used the lobbying firm, Tarplin, Downs & Young LLC to lobby the Federal Government on the 340B Drug Discount issue, and concomitantly, insulin or diabetes. Further, in the same period, both Sanofi and AstraZeneca used the lobbying firm W Strategies, LLC to lobby 340B Drug Discounts. And Sanofi, Eli Lilly, and Novo Nordisk used the common lobbying firm Williams and Jensen, PLLC to lobby the same issue in this same period. Moreover, some of these lobbyists frankly revealed that their lobbying focused on "Executive Orders regarding drug pricing," including Executive Order 13937.

112. This common effort allowed Defendants to coordinate and communicate about their strategies on limiting 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts, for diabetes medications such as analog insulins and incretin mimetics. Defendants were speaking with the same lobbying firms about the same issues at the same time. At the very least, they were communicating indirectly, through these common firms.

113. It is much more likely that Defendants were also communicating directly about their lobbying strategies with their common lobbyists. Significantly, the common lobbying firms—including Tarplin, Downs & Young and Williams and Jensen, PLLC—reported working on these same 340B issues during this same period for the drug manufacturers' association, PhRMA. Each Defendant is a member of PhRMA. Given the common lobbying firms working for each Defendant and their common association in the same time period on the same issues, all in advance of an executive order on those issues, it is most likely that Defendants would have been on common calls to discuss strategy. Upon information and belief, in advance of the President's issuance of Executive Order 13937, Defendants communicated directly with each other about strategies for limiting 340B Drug Discounts.

114. Upon information and belief, Defendants' lobbying efforts focused on the four strategies that the pharmaceutical industry and its advocates had long pursued to limit 340B Drug Discounts: (1) limiting the level of hospital participation in the 340B Program, (2) limiting which patients could qualify for 340B Drug Discounts, (3) requiring that all discounts be passed through to patients, and (4) limiting the availability of Contract Pharmacy 340B Drug Discounts.

115. Defendants lobbying efforts largely failed, as Defendants were unable to obtain meaningful changes to the availability of 340B Drug Discounts through lobbying. The drug companies' perception that Executive Order 13973 was largely meaningless is reflected in the tweets of AIR340B, a drug company association aimed at limiting the scope of the 340B Program, which hosts a webpage dedicated to challenging the propriety of Contract Pharmacy 340B Drug Discounts. *See* AIR340B, "Contract Pharmacies' Troubling Role in the 340B Drug Discount Program" (last visited May 14, 2021). In the wake of the executive order, AIR340B tweeted, "[T]he administration's executive order on insulin and #340B . . . misses the mark by

not targeting the large hospitals;" "this narrow change does not address the myriad of remaining issues that prohibit 340B from currently functioning as it was intended;" and "we are disappointed the administration targeted FQHCs, not DSH hospitals."

116. Given the failure of lobbying efforts, Defendants, upon information and belief, then turned to their plan B, which focused on just one of their strategies—their coordinated withdrawal of Contract Pharmacy 340B Drug Discounts.

IV. After their joint lobbying efforts failed, Defendants coordinated a rollback of Contract Pharmacy 340B Drug Discounts.

A. Defendants imposed their restrictions in near lockstep in the second half of 2020.

117. Defendants engaged in a coordinated campaign to limit Contract Pharmacy 340B Drug Discounts. That plan began as soon as the President's executive order was released, when it became plain that lobbying had not yielded legal changes to curb 340B Drug Discounts for diabetes medicines. While every other major pharmaceutical company continued to offer Contract Pharmacy 340B Drug Discounts, the four Defendants—competitors against each other for diabetes medicines—quickly announced novel restrictions on Contract Pharmacy 340B Drug Discounts. While Defendants did not announce their plans at identical times, they announced restrictions closely enough to each other to prevent covered entities from moving business from one Defendant to another. Defendants' coordinated campaign succeeded in virtually ending Contract Pharmacy 340B Drug Discounts in the three diabetes medication markets they dominated, dramatically raising prices for safety-net hospitals and clinics.

118. On July 24, 2020, the same day that President Trump issued Executive Order 13937, AstraZeneca informed HHS of the drug company's intention to limit Contract Pharmacy 340B Drug Discounts. It did so by letter from Christie Bloomquist, AstraZeneca's Corporate Affairs Vice President for North America, to Rear Admiral Krista Pedley, the Director of

HRSA's Office of Pharmacy Affairs. The letter stated that, "Beginning on October 1, 2020, AstraZeneca plans to adjust [its] approach for the products listed," "such that AstraZeneca will recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy." The products listed included AstraZeneca's incretin mimetics, Bydureon and Byetta.

119. In its July 24th letter to HHS, AstraZeneca did not explain the timing of its sudden change in approach to Contract Pharmacy 340B Drug Discounts. Rather, AstraZeneca made a legal argument based on the text of the 1992 statute, as well as the text of the 1996 notice. The letter also referenced audits that had been taking place since 2017. But, significantly, nothing in the letter explained why AstraZeneca was deciding, in late 2020, to completely change its approach to Contract Pharmacy 340B Drug Discounts. AstraZeneca did not make its plan public until mid-August 2020.

120. Yet, within days of AstraZeneca's privately communicated letter to HRSA, Sanofi publicly announced its sudden plans to impose similarly novel restrictions on Contract Pharmacy 340B Drug Discounts—and on the exact same timeline. Specifically, on or about July 27, 2020, Sanofi informed all 340B Program covered entities that Sanofi would be "implementing a new 340B program integrity initiative." That "initiative" would cut off all Contract Pharmacy 340B Drug Discounts, which had been in place for a decade, unless covered entities provided new consideration to Sanofi. The newly required consideration was entry into a contract to provide sensitive prescription claims data to a Sanofi vendor through a software portal on commercially unreasonable terms. Otherwise, "340B claims data [would] no longer be eligible" for Contract Pharmacy 340B Drug Discounts. Significantly, Sanofi announced that the date it would begin limiting Contract Pharmacy 340B Drug Discounts was October 1, 2020—the same date that

AstraZeneca would limit Contract Pharmacy 340B Drug Discounts, too. Sanofi was, at the time, a $132 billion company; and it would have been virtually impossible for Sanofi to have vetted and cleared such a dramatic and unprecedented change in its pricing practices on a few days' notice.

121. Three weeks later, Eli Lilly informed HHS of the drug company's intention to limit Contract Pharmacy 340B Drug Discounts in nearly the precise manner AstraZeneca had privately outlined in its letter to HHS. By letter dated August 19, 2020, Eli Lilly's Senior Director of Government Strategies sent a letter to Rear Admiral Krista Pedley, the Director of HRSA's Office of Pharmacy Affairs, just as Christie Bloomquist at AstraZeneca had done. The letter stated the same plan as AstraZeneca, albeit commencing one month earlier: "[E]ffective September 1, [2020], we . . . [will] discontinue our practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products except where," primarily, "a covered entity does not have an in-house pharmacy."

122. Eli Lilly added a special exception to permit Contract Pharmacies to pass along certain insulin products at cost. But that exception was infeasible for covered entities and pharmacies, as it required the Contract Pharmacies to fill prescriptions without any fee whatsoever. Specifically, Eli Lilly stated that it would offer the Contract Pharmacy 340B Drug Discount only where "[n]o insurer or payer is billed for the Lilly insulin dispensed" and "[n]either the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing…fee for the Lilly insulin." This exception was so narrow that it was virtually meaningless: Lilly prevented the collection of any revenue by a covered entity to offset the dispensing fee the covered entity would have to pay the Contract Pharmacy. This exception was commercially infeasible, as Eli Lilly understood.

123. Eli Lilly, like AstraZeneca and Sanofi, offered no explanation why suddenly, after a decade of offering Contract Pharmacy 340B Drug Discounts, Eli Lilly decided to stop them in late 2020. The absence of an explanation was particularly strange because, months earlier, Eli Lilly had informed HHS of a much narrower change to its Contract Pharmacy 340B Drug Discounts—ceasing to offer discounts on a single drug, Cialis. Eli Lilly informed HHS of that decision just two months earlier, by letter dated May 18, 2020. But while the May 18 letter cited global concerns with Contract Pharmacies, it announced the decidedly narrower action of simply ceasing to offer discounts on Cialis. In May 2020, Eli Lilly did not inform HHS that it would cease to offer Contract Pharmacy 340B Drug Discounts altogether. Significantly, Eli Lilly did not then announce any restrictions on Contract Pharmacy 340B Drug Discounts for its rapid-acting analog insulins (Humalog and Insulin Lispro), its long-acting analog insulin (Basaglar), or its incretin mimetic (Trulicity). Eli Lilly first announced those restrictions, instead, only in coordination with AstraZeneca and Sanofi.

124. Novo Nordisk waited several more months before announcing that it would stop offering Contract Pharmacy 340B Drug Discounts to hospital covered entities. On December 1, 2020, Novo Nordisk informed HHS of the drug company's policy. In particular, Novo Nordisk, along with its competitors AstraZeneca, Eli Lilly, and Sanofi, would limit the availability of Contract Pharmacy 340B Drug Discounts. The Novo Nordisk restrictions were a variation on the competitors' theme—it would stop offering Contract Pharmacy 340B Drug Discounts to all hospital covered entities. Novo Nordisk announced that this restriction would be effective on January 1, 2021.

B. Defendants' abrupt changes in pricing practices were historically unprecedented.

125. Defendants' abrupt limitation of Contract Pharmacy 340B Drug Discounts were historically unprecedented.

126. Prior to Defendants' actions in late 2020, each company had regularly offered Contract Pharmacy 340B Drug Discounts for a decade.

127. Indeed, prior to Defendants' actions in 2020, the entire pharmaceutical industry—including all of the largest 250 drug companies, as well as every drug company with drugs covered by Medicaid and Medicare Part B—had regularly offered Contract Pharmacy 340B Drug Discounts for their covered outpatient drugs for at least a decade.

128. Moreover, shortly before its coordination with the other Defendants, Eli Lilly had considered withdrawing Contract Pharmacy 340B Drug Discounts and decided against doing so, outside of a very narrow set of certain Cialis formulations. Eli Lilly abruptly changed its approach in coordination with the other Defendants.

C. Defendants—direct competitors in three diabetes medication markets—were alone in imposing these restrictions, as thousands of other pharmaceutical companies did not.

129. Not a single other major pharmaceutical company joined the Defendants in their coordinated scheme to limit or eliminate Contract Pharmacy 340B Drug Discounts.

130. In 2020, two top drug manufacturers—Merck and Novartis—asked covered entities to participate in the same software program mandated by Sanofi. But, unlike Sanofi, neither Merck nor Novartis cut off Contract Pharmacy 340B Drug Discounts for covered entities unwilling to participate. A much smaller drug company, United Therapeutics, announced plans to restrict Contract Pharmacy 340B Drug Discounts, but it has not implemented that policy.

131. It was not until late 2021 that any major drug company implemented any similar restrictions on Contract Pharmacy 340B Drug Discounts. They did so more than a year after Defendants announced their restrictions. Specifically, Boehringer Ingelheim imposed restrictions beginning on August 1, 2021, and Merck imposed restrictions beginning on September 1, 2021. Merck, however, limited its restrictions mainly to antidiabetic drugs, such as Januvia, Janumet, Segluromet, and Steglatro.

132. Defendants comprise fewer than 0.4% of the more than 1,000 drug companies that have signed PPAs with HHS.

133. Defendants, as direct competitors with each other in three key markets for diabetes medications, have restricted Contract Pharmacy 340B Drug Discounts.

134. The other more than 99.6% of drug companies have continued to offer Contract Pharmacy 340B Drug Discounts without restrictions. Those drug companies include some of the largest drug companies, such as Roche, Johnson & Johnson, Pfizer, AbbVie, Amgen, Bristol Myers Squibb, GlaxoSmithKline, Gilead, Bayer, Biogen, Takeda, Bausch Health, Alexion, and Regeneron, as well as more than a thousand others.

135. Defendants' common attribute, as the very few drug companies restricting Contract Pharmacy 340B Drug Discounts, is their joint domination of the three key diabetes medication markets. As of July 2020, Defendants controlled the entire market for each of those markets: (i) rapid-acting analog insulins; (ii) long-acting analog insulins, and (iii) incretin mimetics. They had no competition.

D. Defendants imposed these restrictions, despite Government warnings that doing so could violate other laws.

136. Defendants' novel restrictions were unusual not only because they were imposed after a decade of offering Contract Pharmacy 340B Drug Discounts or because they were

imposed by Defendants alone among major pharmaceutical companies, but also because they were imposed despite warnings by regulators that such restrictions were illegal.

137. On September 2, 2020, HRSA released a public statement to the *340B Report*, an online media outlet, that HHS was "considering whether manufacturer policies [restricting Contract Pharmacy 340B Drug Discounts], including Lilly's, violate the 340B statute and whether sanctions may apply."

138. On September 21, 2020, HRSA posted a letter to its public website warning manufacturers of potentially dire consequences for restricting Contract Pharmacy 340B Drug Discounts. The letter was signed by HHS General Counsel, Robert P. Charrow. The letter was addressed to Eli Lilly, but shared publicly. In it, HRSA stated that it had "significant initial concern with Lilly's new policy" to "cease extending 340B pricing to pharmacies under contract with covered entities." HRSA went so far as to warn Eli Lilly, and, by extension, any other manufacturers who might impose restrictions on Contract Pharmacy 340B Drug Discounts, that a "False Claims Act suit . . . against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors." False Claims Act violations trigger treble damages and penalties.

139. On October 6, 2020, the Office of the Attorney General of the State of Connecticut sent letters to Sanofi, AstraZeneca, and Eli Lilly, "urg[ing] [each] to abandon its recent actions of unilaterally restricting access to low cost drug pricing by covered entities." The letters stated that the companies' "threats to flout federal requirements and discontinue appropriate 340B drug pricing are especially appalling given that these critical safety-net healthcare institutions are on the front lines of our response to the ongoing COVID-19 pandemic." The letters deemed the companies' actions "outrageous." Moreover, the

Connecticut Attorney General stated that "[d]enying outpatient access to appropriate 340B drug pricing is a clear violation of federal law," which "disrupt[s] long-settled expectations and existing contractual arrangements for dispensing 340B drugs." The Attorney General ended his letter with the threat that his "office will not stand idly by while Eli Lilly and other drug companies prioritize profits over access to affordable prescription medication and other critical medical services for vulnerable communities."

140. The next day, the Connecticut Attorney General issued a press release announcing his letters to Sanofi, Eli Lilly, and AstraZeneca. The press release was entitled, "AG Tong Demands Drug Makers Abandon Unlawful Actions Imperiling Access to Affordable Prescriptions for Low-Income Patients." The press release included a hyperlink to the letters to drug manufacturers.

141. On December 20, 2020, HHS General Counsel Robert P. Charrow issued an eight-page single-spaced advisory opinion concluding that restrictions on Contract Pharmacy 340B Drug Discounts were illegal under the terms of Section 340B. *See* HHS General Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020). The opinion noted, in a reference to the actions of Defendants, that "[r]ecently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price" (*i.e.*, with Contract Pharmacy 340B Drug Discounts). *See id.* at 1. The opinion noted that "[f]or 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution." *Id.* at 5 n.5. For reasons detailed in the opinion, HHS concluded that "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling

price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." *Id.* at 8.

142. The same day, HHS issued a press release announcing its advisory opinion. The press release was entitled, "HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies." The press release included a hyperlink to the advisory opinion.

143. More recently, on May 17, 2021, HRSA sent letters to each Defendant demanding that each "restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements." The letters stated HRSA's conclusion that the Defendants' restrictions "are in direct violation of the 340B statute." Moreover, the letters warned each Defendant of potentially massive civil monetary penalties of up to $5,883 per instance of overcharge.

144. Even more recently, on June 18, 2021, the Office of General Counsel for HHS announced its intention to pursue Defendants for unlawfully restricting the availability of Contract Pharmacy 340B Drug Discounts. The Notice withdrew the legal opinion of December 20, 2020, "in the interest of avoiding confusion." But the Notice made clear that "its withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers, including HRSA's May 17, 2021 violation letters concerning restrictions placed on contract pharmacy arrangements."

145. Most recently, on September 22, 2021, HRSA sent letters to each Defendant announcing a referral to the HHS Office of the Inspector General (OIG) for violating the law. Each letter recounted that on "May 17, 2021, HRSA instructed" each Defendant "to comply with its 340B statutory obligations and to immediately begin offering [340B Drug Discounts] to

covered entities that dispense the discounted medications through their contract pharmacy arrangements," and that HRSA had informed each Defendant "that continued failure to provide the 340B price to covered entities utilizing contract pharmacies could result in civil monetary penalties." The letters then stated that, given each Defendant's "continued refusal to comply, HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule."

146. Despite these warnings from regulators, Defendants persisted in restricting access to Contract Pharmacy 340B Drug Discounts.[5]

CONSPIRACY ALLEGATIONS

147. Defendants engaged in concerted action to restrict Contract Pharmacy 340B Drug Discounts.

I. Defendants are Horizontal Competitors.

148. Defendants directly compete with one another, including in their sales of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

A. Defendants' rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics are in direct competition.

1. Sanofi, Eli Lilly, and Novo Nordisk are in direct competition in the production and sale of rapid-acting analog insulins.

149. Defendants Sanofi, Eli Lilly, and Novo Nordisk directly compete against each other in manufacturing and/or selling rapid-acting analog insulins.

[5] By letter dated February 2, 2021, however, Sanofi purported to limit its restrictions to five covered entity types: consolidated health center programs, disproportionate share hospitals, critical access hospitals, rural referral centers, and sole community hospitals. These restrictions continue to restrict Plaintiffs' abilities to obtain Contract Pharmacy 340B Drug Discounts.

150. Defendants' competing rapid-acting analog insulins include Sanofi's Apidra and Admelog; Eli Lilly's Humalog and Insulin Lispro; and Novo Nordisk's Fiasp, Novolog, and Insulin Aspart.

151. Apidra, Admelog, Humalog, Insulin Lispro, Fiasp, Novolog, and Insulin Aspart are each clinically equivalent and therapeutically interchangeable with one another.

152. The FDA categorizes drugs into pharmacological classes. The FDA categorizes Apidra, Admelog, Humalog, Insulin Lispro, Fiasp, Novolog, and Insulin Aspart in the pharmacological class of insulin analog. The only other drugs in the same pharmacological class are the long-acting analog insulins listed below.

153. For the last decade, including during and since July 2020, Defendants Sanofi, Eli Lilly, and Novo Nordisk have competed with each other in the manufacture and sale of rapid-acting analog insulins.

2. Sanofi, Eli Lilly, and Novo Nordisk are in direct competition in the production and sale of long-acting analog insulins.

154. Defendants Sanofi, Eli Lilly, and Novo Nordisk directly compete against each other in manufacturing and/or selling long-acting analog insulins.

155. Defendants' competing long-acting analog insulins include Sanofi's Lantus and Toujeo; Eli Lilly's Basaglar; and Novo Nordisk's Levimir and Tresiba.

156. Lantus, Toujeo, Basaglar, Levimir, and Tresiba are each clinically equivalent and therapeutically interchangeable with one another.

157. The FDA categorizes Lantus, Toujeo, Basaglar, Levimir, and Tresiba in the same pharmacological class of insulin analog. The only other long-acting analog insulin in this pharmacological class is a new entrant, Semglee, manufactured by Mylan and Biocon Ltd, which

was not being sold in the United States in July 2020. The only other drugs categorized in the insulin analog pharmacological class are the rapid-acting analog insulins listed above.

158. Since 2015, including during and since July 2020, Defendants Sanofi, Eli Lilly, and Novo Nordisk have competed with each other in the manufacture and sale of long-acting analog insulins.

3. Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca are in direct competition in the production and sale of incretin mimetics.

159. Defendants Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca directly compete against each other in manufacturing and/or selling incretin mimetics.

160. Defendants' competing incretin mimetics include Sanofi's Adlyxin; Eli Lilly's Trulicity; Novo Nordisk's Victoza, Ozempic, and Rybelsus; and AstraZeneca's Bydureon and Byetta.

161. Adlyxin, Trulicity, Victoza, Ozempic, Rybelsus, Bydureon, and Byetta are each clinically equivalent and therapeutically interchangeable with one another.

162. The FDA categorizes Trulicity, Victoza, Ozempic, Rybelsus, Bydureon, and Byetta in the pharmacological class of GLP-1 Receptor Agonist. The only other drug in the same pharmacological class, Saxenda (another Novo Nordisk drug), is FDA-approved for weight management, not diabetes.

163. Since 2016, including during and since July 2020, Defendants Sanofi, Eli Lilly, Novo Nordisk and AstraZeneca have competed with each other in the manufacture and sale of incretin mimetics.

B. Defendants have virtually no other competitors for their rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

164. Defendants' products dominate each market.

1. Defendants face no competition for rapid-acting analog insulins.

165. As of July 2020, Defendants sold the only available rapid-acting analog insulins: Sanofi's Apidra and Admelog; Eli Lilly's Humalog and Insulin Lispro; and Novo Nordisk's Fiasp, Novolog, and Insulin Aspart.

166. That remains true today.

167. No other rapid-acting analog insulins are available in the United States.

2. Defendants faced no competition for long-acting analog insulins.

168. As of July 2020, Defendants sold the only available long-acting analog insulins: Sanofi's Lantus and Toujeo; Eli Lilly's Basaglar; and Novo Nordisk's Levimir and Tresiba.

169. These drugs continue to dominate the market today.

170. The sole competitive drug, Semglee, has a long way to go before it can capture market share. Around October 2020, Mylan and Biocon introduced Semglee as another long-acting analog insulin. But competition within the diabetic medications market is slow-moving. As Biocon explained on April 29, 2021, it "witnessed [only] a modest uptake of biosimilar Insulin Glargine (*Semglee**)* following its launch in FY21." Biocon attributed the slow increase in market share to "the timing of approval impacting formulary contracting cycles for CY21." *See* Biocon Ltd., "Biocon Q4FY21 Revenue at Rs2,044 Cr, Up 26%," (Apr. 29, 2021), at https://www.biocon.com/biocon-q4fy21-results/. Biocon's Chief Operating Officer, Shreehas P. Tambe has explained that there was "a slower than usual ramp-up for these products," and "other similar products in the market in the first 12-months have had a single-digit market share," before they "get to preferred or exclusive formulary status." Biocon Limited Q3 FY21 Earning Conference Call Transcript (Jan. 22, 2021), at https://www.biocon.com/biocon-q4fy21-results/.

3. Defendants face no competition for incretin mimetics.

171. As of July 2020, Defendants sold the only available incretin mimetics: Sanofi's Adlyxin; Eli Lilly's Trulicity; Novo Nordisk's Victoza, Ozempic, and Rybelsus; and AstraZeneca's Bydureon and Byetta.

172. That remains true today.

173. No other incretin mimetics are available in the United States.

C. Defendants face few competitors—mainly, only each other—in selling rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics sales.

174. Few competitors compete in the manufacture and sale of rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics.

175. The rapid-acting analog insulin market is dominated by only three companies—Sanofi, Eli Lilly, and Novo Nordisk.

176. The long-acting analog insulin market is dominated by only three companies—Sanofi, Eli Lilly, and Novo Nordisk.

177. The incretin mimetic market is dominated by only four companies—Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca.

II. Defendants Restricted Contract Pharmacy 340B Drug Discounts in Parallel.

178. Defendants acted in parallel to restrict Contract Pharmacy 340B Drug Discounts.

179. Defendants announced their planned restrictions in near lockstep, between July 2020 and December 2020. On July 24, 2020, AstraZeneca privately informed HHS of its planned restrictions. Three days later, on July 27, 2020, Sanofi announced that it would impose its restrictions. Three weeks later, on August 19, 2020, Eli Lilly informed HHS of its restrictions. And within three-and-a-half months, on December 1, 2020, Novo Nordisk informed HHS of its restrictions.

180. Likewise, Defendants imposed their restrictions in near lockstep, between September 2020 and January 2021. Eli Lilly imposed its restrictions beginning on September 1, 2020. Both AstraZeneca and Sanofi imposed their restrictions beginning just one month later, on October 1, 2020. And Novo Nordisk imposed its restrictions just three months later, on January 1, 2021.

181. Each Defendant imposed similar restrictions on Contract Pharmacy 340B Drug Discounts. AstraZeneca, Eli Lilly, and Novo Nordisk, with minor and largely insignificant exceptions, limited the availability of all Contract Pharmacy 340B Drug Discounts. So too, Sanofi limited the availability of all Contract Pharmacy 340B Drug Discounts, with an exception for covered entities agreeing to provide Sanofi with sensitive prescription information through Sanofi's software vendor on commercially unreasonable terms. The net effect of each restriction was the same—ending nearly all Contract Pharmacy 340B Drug Discounts for AstraZeneca, Eli Lilly, Novo Nordisk, and Sanofi drugs.

182. These announced changes were close enough in time to effectively prevent any covered entity from steering prescriptions to competitors (*i.e.*, other Defendants). Because covered entities prescribe drugs, new prescriptions require new doctor-patient interactions. Those occur only periodically. Accordingly, it takes many months to transition a provider's patients from one preferred drug to another. Defendants announced their restrictions on Contract Pharmacy 340B Drug Discounts close enough in time to one another that covered entities could not, and did not, make significant progress in transitioning patients from one drug (for which Contract Pharmacy 340B Drug Discounts had been made unavailable) to another drug (for which Contract Pharmacy 340B Drug Discounts were still, temporarily, available).

III. Defendants Conspired in Imposing Their Parallel Restrictions.

183. The nature and timing of the parallel conduct described above, set within the context of this industry, is strongly suggestive of conspiracy, rather than of independent action. Among the facts plausibly suggestive of an agreement are the following: (i) acting alone in eliminating or restricting the Contract Pharmacy 340B Drug Discounts would have been against any single Defendant's unilateral self-interest because it would risk market share; (ii) Defendants shared a common motive to raise prices by avoiding the Contract Pharmacy 340B Drug Discount, if they could do so jointly; (iii) Defendants' restrictions were historically unprecedented; (iv) indeed, Defendants' restrictions remain anomalous in the pharmaceutical industry; (v) there are a small number of competitors in the rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics areas (*i.e.*, the four Defendants); (vi) there are significant barriers to entry for new competitors; (vii) Defendants engaged in a high volume of communications immediately in advance of their concerted action; (viii) Defendants' alleged antirust conspiracies in the past, including fixing prices for rapid-acting analog insulin and long-acting analog insulin, and their alleged similar price manipulation of these same drugs; and (ix) within three days of AstraZeneca privately informing HRSA of its plan to restrict Contract Pharmacy 340B Drug Discounts, Sanofi publicly announced its corresponding restrictions, which is too close in time to be a coincidence.

A. Restricting Contract Pharmacy 340B Drug Discounts would have been against any single Defendant's self-interest.

184. It would have been against any single Defendant's self-interests to restrict Contract Pharmacy 340B Drug Discounts. Doing so, while a Defendant's competitors continued to offer Contract Pharmacy 340B Drug Discounts, would have put the Defendant at a significant competitive disadvantage.

185. If a single Defendant had restricted Contract Pharmacy 340B Drug Discounts, its market share and sales volumes in the financially important markets for rapid-acting analog insulins, long-acting analog insulins, or incretin mimetics would have been seriously threatened.

186. Access to Contract Pharmacy 340B Drug Discounts is a critically important economic issue for covered entities. Indeed, access to such discounts is oftentimes more important than other attributes of drug pricing. The reason why is that hospitals and clinics may not directly bear the burden of higher drug pricing. Those burdens often fall on third-party payors, such as insurers and government healthcare programs. By contrast, covered entities directly benefit from the availability of 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts, which produce 340B Savings for covered entities. Where a series of drugs are clinically equivalent and therapeutically interchangeable, a covered entity has a strong economic incentive to favor the drug(s) that provide access to 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts.

187. Covered entities' drug preferences are generally more important for Defendants' drug sales and market share than individual consumer preferences. Consumers do not choose prescription medications directly; they must be prescribed by a physician. And physicians are often employed by or associated with covered entities, which can share preferences with physicians as to preferred drugs among a class of clinically equivalent and therapeutically interchangeable medications.

188. If a single Defendant restricted Contract Pharmacy 340B Drug Discounts on its drug, then covered entities, including 340B hospitals, could have taken steps to steer their prescribing physicians towards prescribing the competing drugs that offered Contract Pharmacy 340B Drug Discounts, as the drugs are all clinically equivalent and therapeutically

interchangeable. And covered entities would have had strong economic incentives to do so to generate the 340B Savings that the 340B Program was designed to produce for covered entities.

189. Defendants knew that their drugs were considered by the medical community as clinically equivalent and therapeutically interchangeable with the other Defendants' drugs.

190. Defendants understood that covered entities would have strong incentives to prescribe drugs with Contract Pharmacy 340B Drug Discounts, instead of drugs for which manufacturers had restricted Contract Pharmacy 340B Drug Discounts.

191. Defendants understood that covered entities would have taken steps to prescribe competing drugs that offered Contract Pharmacy 340B Drug Discounts, instead of drugs for which manufacturers had restricted Contract Pharmacy 340B Drug Discounts.

192. Defendants understood that, if they acted alone, they were at risk of losing sales and market share, both in the short-term and the long-term.

193. For these reasons and others, Defendants had strong incentives not to act alone in restricting Contract Pharmacy 340B Drug Discounts.

194. Drug manufacturers' strong incentives not to act alone in restricting Contract Pharmacy 340B Drug Discounts is illustrated by the actions of other drug companies which did not engage in a conspiracy to restrict Contract Pharmacy 340B Drug Discounts. More than 1,000 other drug companies participate in the 340B Program. They sell drugs in markets distinct from the markets for rapid-acting analog insulins, long-acting analog insulins, or incretin mimetics. Those 1,000-plus other drug companies did not impose restrictions on Contract Pharmacy 340B Drug Discounts because, just as for Defendants (if they had acted alone), imposing any such restrictions would be competitively disadvantageous and against their individual economic self-interest.

B. Defendants had a common motive to conspire.

195. Defendants had a common motive to conspire to restrict Contract Pharmacy 340B Drug Discounts, collectively.

196. If Defendants could together raise prices by restricting Contract Pharmacy 340B Drug Discounts, without decreasing any Defendant's sales or market share, each Defendant would earn higher profits, thus increasing their already substantial annual sales revenues.

197. Defendants understood that if they collectively restricted Contract Pharmacy 340B Drug Discounts, they would collectively make higher profits.

198. Defendants understood that if they collectively restricted Contract Pharmacy 340B Drug Discounts, they would not need to compete for covered entity prescribing preferences by offering Contract Pharmacy 340B Drug Discounts. Each Defendant controlled U.S. market shares worth hundreds of millions, or billions, of dollars annually, and none wanted to put those market shares at further risk by competing as to the availability of Contract Pharmacy 340B Drug Discounts. Defendants understood that if they jointly restricted Contract Pharmacy 340B Drug Discounts, those discounts would be equally unavailable for each of the competitors' drugs.

C. Defendants' sudden restrictions were historically unprecedented.

199. Defendants' restrictions were imposed suddenly after a decade of offering Contract Pharmacy 340B Drug Discounts.

200. Defendants and all other drug companies participating in Medicaid or Medicare Part B had consistently offered Contract Pharmacy 340B Drug Discounts for at least decade. "For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution." *See* HHS General Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program at 5 n.5 (Dec. 30, 2020).

201. After a decade of consistently offering Contract Pharmacy 340B Drug Discounts, Defendants suddenly announced restrictions on Contract Pharmacy 340B Drug Discounts during the second half of 2020.

202. These changes were made despite warnings from regulators that such changes were viewed as illegal. These changes were made when no other drug manufacturer imposed similar restrictions.

203. The sudden, historically unprecedented change made by four direct competitors within the drug industry is indicative of conspiracy, rather than independent action.

D. Defendants' restrictions remain anomalous in the pharmaceutical industry.

204. Defendants imposed restrictions, even though nearly the entire remainder of the pharmaceutical industry—thousands of manufacturers participating in the 340B Drug Discount Program—did not.

205. More than 99.6% of drug companies continue to offer Contract Pharmacy 340B Drug Discounts without restrictions. Those drug companies include some of the largest drug companies, such as Roche, Johnson & Johnson, Pfizer, AbbVie, Amgen, Bristol Myers Squibb, GlaxoSmithKline, Gilead, Bayer, Biogen, Takeda, Moderna, Bausch Health, Alexion, and Regeneron, as well as more than a thousand others.

206. The fact that Defendants—as each other's sole competitors as of July 2020 for rapid-acting analog insulins, long-acting analog insulins, and incretin mimetics—restricted Contract Pharmacy 340B Drug Discounts, while nearly the entire remainder of the industry did not, strongly suggests that Defendants acted in coordination with each other, rather than out of their own self-interest.

207. Moreover, the fact that Eli Lilly considered restricting Contract Pharmacy 340B Drug Discounts earlier in 2020, but decided against doing so (except for a narrow band of Cialis

formulations) until other Defendants also decided to do so, strongly suggests that Defendants acted in coordination with each other, rather than out of their self-interest. If it had been in Eli Lilly's self-interest to independently limit all Contract Pharmacy 340B Drug Discounts, it would have done so when it limited Cialis discounts.

E. The small number of competitors selling rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics facilitates conspiracy.

208. The existence of few competitors for a product makes that product more conducive to a price-fixing conspiracy, such as the elimination, reduction, or restriction of a discount.

209. Defendants Sanofi, Eli Lilly, and Novo Nordisk—just three companies—are the sole competitors manufacturing and selling rapid-acting analog insulins in the United States.

210. Defendants Sanofi, Eli Lilly, and Novo Nordisk—again just three companies—were the sole competitors manufacturing and selling long-acting analog insulins in the United States as of July 2020. A fourth competitor, Mylan/Biocon, recently joined the competition, but has had insufficient opportunities to gain market share. Defendants Sanofi, Eli Lilly, and Novo Nordisk still compete in selling long-acting analog insulins among just four competitors, and Defendants Sanofi, Eli Lilly, and Novo Nordisk dominate the market, with more than 90% of sales of long-acting analog insulins.

211. Defendants Sanofi, Eli Lilly, Novo Nordisk, and AstraZeneca—just four companies—are the sole competitors manufacturing and selling incretin mimetics in the United States.

212. Because so few firms compete in the manufacture and sale of rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics, an effective pricing conspiracy relating

to those drugs requires the coordination of only a few firms. That makes the market more conducive to conspiracy.

F. There are significant barriers for any new competitors.

213. Defendants' conspiracy is further facilitated by significant barriers to entry, which effectively prevent would-be competitors from seeking a competitive advantage by offering Contract Pharmacy 340B Drug Discounts to compete against Defendants.

214. New market entrants face significant barriers to entry into the rapid-acting analog insulin, long-acting analog insulin, and incretin mimetics markets. These barriers include intellectual property, costs of manufacture, and expenses related to regulatory oversight.

215. As recently reported by the Center for Biosimilars, in the article, "Panel: Insulin Biosimilar Competition May Be Scant at Best," industry experts have explained that "[i]t's not easy to break into the insulin market." "Insulin is a biologic that is very difficult to consistently produce at high purity in large volumes that would be necessary for distribution, and very few manufacturers have the resources to perfect this process and convince regulators that they can get it right, the panelists [at the Festival of Biologics USA] said." "Many companies have attempted to bring rival insulin products . . . and have failed because the pharmacokinetics of these products are extremely difficult to match precisely with originator products, [Sundar] Ramanan, [PhD, BMA, vice president and head of Global Regulatory Affairs for Biocon] said." "'That's barrier number 1. Barrier number 2 is we need to have economies of scale, and that requires a large capital investment, and not many companies have that to combine with the science. This limits the number of players that are coming in beyond the ones that are truly committed.'" *See* Tony Hagen, "Panel: Insulin Biosimilar Competition May Be Scant at Best," The Center for Biosimilars (Mar. 31, 2021), *at* https://www.centerforbiosimilars.com/view/panel-insulin-biosimilar-competition-may-be-scant-at-best.

216. Those barriers to entry and others allow Defendants to engage in a pricing conspiracy among themselves without being threatened by other firms.

G. In advance of the conspiracy, Defendants were engaged in high levels of communication that gave them ample opportunity to conspire.

217. Defendants had ample opportunity to conspire and were engaged in high levels of communications in advance of their imposition of restrictions.

218. The Defendants engaged in high levels of communication about the subjects of the conspiracy through lobbying. In the second and third quarters of 2020, before and at the time of the commencement of the conspiracy, Defendants were engaged in a joint lobbying campaign. That campaign related to 340B Drug Discounts and diabetes medicines. Defendants used common lobbyists and appear to have communicated directly with each other about their lobbying campaign. It is likely during that joint lobbying effort, Defendants planned their restrictions on Contract Pharmacy 340B Drug Discounts as a fallback position if their lobbying efforts failed. When their lobbying efforts failed, Defendants imposed coordinated restrictions on Contract Pharmacy 340B Drug Discounts.

219. The Defendants also engaged in high levels of communications through industry associations, including PhRMA. Each Defendant is a member of PhRMA and on its Board of Directors. In July 2020, PhRMA's Board of Directors included Eli Lilly's CEO, David Ricks (serving as Chairman-Elect); Sanofi's CEO, Paul Hudson; Novo Nordisk's Executive Vice President & Head of North America Operations, Douglas J. Langa; and AstraZeneca's Executive Director & CEO, Pascal Soriot. The most prominent advocacy issue on the PhRMA website, listed first among the only two issues with graphic displays, was "340B." And the 340B page to which that graphic was hyperlinked present "Contract Pharmacies" as an "Area[] for Needed 340B Reform." Defendants, as PhRMA Board members, likely communicated among

themselves about PhRMA's most prominent advocacy issue, 340B Drug Discounts, including Contract Pharmacy 340B Drug Discounts.

H. Most Defendants have been alleged to have engaged in antitrust conspiracies and price manipulation for diabetes medications in the past.

220. Separate and apart from their coordination of restrictions on Contract Pharmacy 340B Drug Discounts, Eli Lilly, Sanofi, and Novo Nordisk have been alleged to have conspired to fix prices on rapid-acting analog insulin and long-acting analog insulin, allowing them to raise prices in lockstep. Private federal court litigation was filed based on those claims. *See generally* Amended Complaint, *In re Direct Purchaser Insulin Pricing Litig.*, 3:20-cv-03426 (D.N.J. filed Nov. 6, 2020).

221. Similarly, Eli Lilly, Sanofi, and Novo Nordisk have been charged with wrongfully colluding with pharmacy benefit managers (PBMs) to artificially raise insulin prices. Both private and Government entities are pursuing these claims. *See generally* Third Amended Complaint, *In re Indirect Purchaser Insulin Pricing Litig.*, 3:17-00699 (D.N.J. Apr. 20, 2021) (presenting RICO and consumer fraud claims, among others); *see also* Complaint, *Minnesota v. Sanofi-Aventis US LLC*, 3:18-cv-14999 (D.N.J.) (pursuing unjust enrichment and consumer fraud claims). Moreover, other government entities have reached similar conclusions. On January 14, 2021, the Senate Finance Committee issued a report on its two-year investigation "into the skyrocketing price of insulin," concluding, as stated by Committee Chair Senator Chuck Grassley, that "[t]his industry is anything but a free market." *See* United States Senate Committee on Finance, "Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs That Keep Prices High: Bipartisan Investigation on Rising Insulin Costs Finds Skyrocketing Prices are a Result of Companies Putting Profits Over Consumers' Interest" (Jan. 14, 2021). And, most recently, on June 8, 2021, the Attorney

General for the State of Mississippi filed suit against the companies and PBMs for "working in tandem to manipulate and inflate insulin prices." Attorney General Lynn Fitch, Press Release, "AG Lynn Fitch Files Lawsuit Against Insulin Manufacturers and PBMs Over Insulin Pricing Scheme," (June 8, 2021).

222. In addition to these public charges, there are reported investigations of similar conduct by the Attorneys General of Colorado, New Mexico, New York, Vermont, and Washington.

I. AstraZeneca and Sanofi, the first two conspirators to reveal restrictions, acted too closely in time to be coincidental, especially because AstraZeneca did not publicly reveal its plans.

223. Defendants coordinated their restrictions in a manner that cannot adequately be attributed to either coincidence or conscious parallelism. This is best illustrated by the first two Defendants to reveal their restrictions—AstraZeneca and Sanofi.

224. AstraZeneca was the first Defendant to reveal its plans to restrict Contract Pharmacy 340B Drug Discounts. But it did not do so publicly. Rather, AstraZeneca informed its regulator, HRSA, that it would restrict Contract Pharmacy 340B Drug Discounts beginning on October 1, 2020. AstraZeneca provided that information to HRSA on July 24, 2020. AstraZeneca did not publish its plans at that time.

225. Yet, Sanofi, the second Defendant to reveal its plans to restrict Contract Pharmacy 340B Drug Discounts, did so within three days of AstraZeneca's non-public announcement. Moreover, Sanofi revealed that it too would implement those restrictions beginning on October 1, 2020, the same date that AstraZeneca had communicated privately to HRSA.

226. The timing coordination between AstraZeneca and Sanofi cannot be attributed to Sanofi responding to AstraZeneca's letter to HRSA revealing its plans because AstraZeneca did not make any public announcement in July about its plans. Nor can the coordination be

attributed to coincidence. After at least a decade of offering Contract Pharmacy 340B Drug Discounts, the odds of two direct competitors—AstraZeneca and Sanofi—revealing novel restrictions, starting on the same day (October 1, 2020), just three days apart are near zero.

227. The coordination between AstraZeneca and Sanofi is a result of conspiracy, not coincidence. That conspiracy extended to all of the Defendants. Indeed, the conspiracy was most effective only with the participation of each of the Defendants.

ANTITRUST INJURY

I. Defendants' conspiracy has restrained competition.

228. Defendants' actions have restrained competition by eliminating pricing discounts that otherwise would have been available to the Plaintiffs and Class Members.

229. Defendants' conspiracy has been effective at allowing them to increase their profits by restricting Contract Pharmacy 340B Drug Discounts, without threatening any Defendant's market share and by protecting each Defendant from competition on discounts.

230. Because each Defendant announced and/or imposed its restrictions within a relatively short number of months, covered entities were unable to effectively respond. The time needed to move patients from one drug to another is generally measured in months. The Defendants coordinated their restrictions in near-enough lockstep to prevent covered entities from moving patients.

231. Through their coordination, Defendants have avoided a significant form of price competition, *i.e.*, on Contract Pharmacy 340B Drug Discounts.

232. Defendants have profited by billions of dollars by restricting Contract Pharmacy 340B Drug Discounts.

II. Plaintiffs have been harmed by Defendants' conspiracy.

233. Plaintiffs and other covered entities have been injured by Defendants' restraint on competition.

234. Defendant drug companies, as horizontal competitors, coordinated their pricing policies in a successful effort to limit access to Contract Pharmacy 340B Drug Discounts, while avoiding competition with one another on the availability of discounts. This has permitted Defendants to profit at the expense of the covered entities purchasing their drugs, thereby threatening to reduce the healthcare services and discounts available to Plaintiffs' and other covered entities' patients.

235. Horizontal competitors who coordinate their pricing policies engage in "competition-reducing" conduct. The 340B covered entities transact in the commerce directly affected by the conduct and are thus "within that area of the economy endangered by the breakdown of competitive conditions." They have been injured in their business and property as a result and have been unable to offer the level of healthcare services to patients as they would have been able to offer absent Defendants' conduct.

236. Covered entities have been injured by losing access to 340B Savings. Before Defendants' conspiracy, each Defendant offered drugs to covered entities for purchase with Contract Pharmacy 340B Drug Discounts. As a result of the conspiracy, and as its aim, Defendants no longer offer such discounts to covered entities. The covered entities, including Plaintiffs, have lost the ability to generate 340B Savings as a result and, consequently, have also lost the ability to provide the range of healthcare services and savings for patients that they would have been able to offer absent Defendants' conduct.

237. These losses are quantifiable in at least two distinct ways.

238. *First*, at times, covered entities have purchased Defendants' drugs for dispensing at Contract Pharmacies without access to the Contract Pharmacy 340B Drug Discounts. Covered entities, including Plaintiffs, have been overcharged for those purchases because the purchase price did not include the 340B Drug Discount. The Complaint refers to these damages as "overcharges."

239. *Second*, and quite often, covered entities have not purchased drugs for dispensing at Contract Pharmacies because of their lost access to Contract Pharmacy 340B Drug Discounts. In those cases, the drugs that would have been purchased by the covered entities have been purchased by the Contract Pharmacies on the Contract Pharmacies' own accounts because, among other reasons, the unavailability of Contract Pharmacy 340B Drug Discounts has made the covered entities' purchase of the drugs economically impracticable. Covered entities can show and quantify, through pharmacy dispensing data and otherwise, 340B-eligible transactions that would have been filled with 340B Drugs if the Defendants had not restricted access to Contract Pharmacy 340B Drug Discounts, and, therefore, can quantify the 340B Savings lost as a consequence of Defendants' conspiracy. The Complaint refers to these damages as "lost 340B Savings revenues."

240. Together, overcharges, lost 340B Savings revenues, and the threat of ongoing and continued overcharges and lost 340B Savings revenues have injured Plaintiffs and other covered entities and have reduced and/or threaten to reduce the range of healthcare services and options for the patients and communities served by Plaintiffs and other covered entities, including the uninsured and underinsured.

III. Only Covered Entities have been Directly Harmed by the Defendants' Conspiracy.

241. Covered entities are the only actors that have been directly harmed by the conspiracy, while their patients and communities have been indirectly harmed. By contrast,

wholesalers that deliver drugs have not been directly harmed because they do not retain any portion of the Contract Pharmacy 340B Drug Discounts. Those discounts are made available by the Defendants only to the covered entities. Because 340B Drug Discounts exist by reason of a statutory obligation that runs only to the 340B covered entities, wholesalers were never overcharged and suffer no antitrust injury on account of the Defendants' illegal agreement to restrict Contract Pharmacy 340B Drug Discounts. Accordingly, only covered entities—and not wholesalers—have suffered antitrust injuries.

242. Apart from covered entities, there are no other efficient enforcers. No other class of persons or entities has any self-interest to vindicate the public interest in antitrust enforcement because no other class of persons or entities has directly suffered as a result of the Defendants' conspiracy.

CLASS ALLEGATIONS

243. Pursuant to Federal Rule of Civil Procedure 23, Plaintiffs bring this action on behalf of the following class:

> All covered entities in the 340B Program with Contract Pharmacy arrangements in place, and which have issued prescriptions for Defendants' drug products since September 1, 2020.

244. There are thousands of Class Members geographically dispersed through the United States. Joinder of all Members of the Class is thus impracticable.

245. Class Members are readily identifiable from public records.

246. Plaintiffs' claims are typical of the claims of the Class embers. Plaintiffs' interests are not antagonistic to the claims of the other Class Members, and Plaintiffs have no material conflicts with any other Class Members that would make class certification inappropriate.

247. Plaintiffs and all class members were damaged by the same wrongful conduct of Defendants. Plaintiffs and all Class Members were unable to obtain Contract Pharmacy 340B Drug Discounts from Defendants and, accordingly, have standing.

248. Plaintiffs will fairly and adequately protect and represent the interests of all Class Members. Plaintiffs' interests are consistent with, and not antagonistic to, those of the class members.

249. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular expertise pursuing class action litigation involving alleged antitrust violations.

250. Questions of law and fact common to Plaintiffs and Class Members predominate over questions that may affect only individual Class Members because the Defendants have acted on grounds generally applicable to the entire class. Determining damages with respect to the class as a whole is thus appropriate.

251. The predominant common legal and factual questions applicable to all Class Members include, but are not limited to, the following:

a. Whether Defendants participated in a contract, combination, or conspiracy to fix prices by restricting access to Contract Pharmacy 340B Drug Discounts;

b. The duration and extent of the alleged contract, combination, or conspiracy;

c. Whether such a contract, combination, or conspiracy is a *per se* violation of the Sherman Act and/or State laws;

d. Whether, and to what extent, Defendants' antitrust violations caused injury to Plaintiffs and Class Members; and

e. The nature and scope of injunctive relief necessary to restore a competitive market and remove the effects of Defendants' conspiracy.

252. These common questions do not vary among the Class Members and predominate over questions affecting only individual class members. The Court may and the jury may thus resolve these issues without reference to the individual circumstances of any Member of the Class.

253. Class action treatment is a superior method for the fair and efficient adjudication of the claims asserted by all Class Members. Such treatment will permit many similarly situated entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender.

254. The benefits of proceeding through a class mechanism, including providing all Class Members a method for obtaining redress on claims that they could not practicably pursue individually, substantially outweigh potential difficulties in the management of this litigation as a class action.

FIRST CLAIM—FEDERAL ANTITRUST VIOLATIONS
(Injunctive relief and treble damages for lost 340B Savings revenue)

255. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

256. Defendants and their co-conspirators entered into, established, and maintained a continuing contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

257. In formulating and effectuating their contract, combination, or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix the prices of drugs by agreeing to coordinate and

eliminate, reduce, or limit the availability of Contract Pharmacy 340B Drug Discounts in a manner that deprived covered entity purchasers in the United States of a significant mechanism of price competition.

258. The contract, combination, or conspiracy had the direct, substantial, and reasonably foreseeable effect upon commerce within the United States of: (a) increasing prices available to Plaintiffs and Class Members for drugs offered by Defendants, by artificially raising or fixing such prices by eliminating Contract Pharmacy 340B Drug Discounts; (b) depriving Plaintiffs and Class Members of 340B Savings revenue; (c) depriving Plaintiffs and Class Members of free, open, and unrestricted competition in the sale of drugs offered by Defendants, by restricting Contract Pharmacy 340B Drug Discounts; and (d) unlawfully restraining, suppressing, or eliminating competition in the prices paid for Defendants' drugs, by eliminating, reducing, or limiting the availability of Contract Pharmacy 340B Drug Discounts.

259. Defendants' contract, combination, or conspiracy was *per se* unlawful price-fixing.

260. Each Defendant has committed at least one overt act to further the conspiracy alleged, including by eliminating, reducing, or limiting the availability of Contract Pharmacy 340B Drug Discounts.

261. The conspiracy is having its intended effect, as Defendants have been benefiting from their collusion and the elimination of competition, both of which artificially inflated the prices of Defendants' drugs for Plaintiffs and Class Members at Contract Pharmacies and deprived Plaintiffs and Class Members of 340B Savings revenue.

262. As a result of Defendants' unlawful conduct, Plaintiffs and other Class Members have been and are being injured in their business and property in that they have been losing 340B

Savings through the eliminated, reduced, or limited availability of Contract Pharmacy 340B Drug Discounts, specifically, through lost 340B Savings revenues.

263. Plaintiffs and other Class Members are entitled to treble damages, along with costs and attorneys' fees, as per Section 4 of the Clayton Act, 15 U.S.C. § 15.

264. Defendants' conduct continues to threaten similar loss and damage in violation of the antitrust laws.

265. Plaintiffs and other Class Members are entitled to injunctive relief to prevent Defendants' illegal conduct and remove all of the lingering effects of such conduct, along with costs and attorneys' fees, as per Section 16 of the Clayton Act, 15 U.S.C. § 26.

SECOND CLAIM—STATE ANTITRUST CLAIMS
(Damages for overcharges and lost 340B Savings revenue)

266. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

267. Beginning at least as early as July 24, 2020 (the exact date being unknown to Plaintiffs and within the exclusive knowledge of Defendants), Defendants entered into, established, and maintained a continuing contract, combination, or conspiracy in unreasonable restraint of trade.

268. The purpose and effect of the conspiracy was to artificially fix and maintain the prices of 340B drugs by agreeing to eliminate, reduce, or limit the availability of Contract Pharmacy 340B Drug Discounts in a manner that deprived Plaintiffs and Class Members of a significant mechanism of price competition.

269. The contract, combination, or conspiracy had a direct, substantial, and reasonably foreseeable effect upon commerce within the United States and within each of the States by: (a)

increasing prices paid by Plaintiffs and Class Members for 340B Drugs sold by Defendants; (b) depriving Plaintiffs and Class Members of 340B Savings that they would otherwise have received in the absence of the conspiracy; and (c) depriving Plaintiffs and Class Members of free, open, and unrestricted competition in the purchase of 340B Drugs sold by Defendants.

270. As a result of Defendants' unlawful conduct, Plaintiffs and other Class Members have been injured in their business and property by paying inflated prices for 340B Drugs and/or by being deprived of 340B Savings.

271. By engaging in the conduct described above, Defendants formed a contract, combination, or conspiracy in restraint of trade in violation of the following State laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Arizona.

   i. In accordance with the requirements of Ariz. Rev. Stat. § 44-1415, contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Mark Brnovich, Attorney General of Arizona, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

b. Cal. Bus. & Prof. Code §§ 16720, and 16750(a), *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of California.

c. Conn. Gen. Stat. §§ 35-3, et seq., with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Connecticut.

d. D.C. Code §§ 28-4501, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the District of Columbia.

e. 740 Ill. Comp. Stat. §§ 10/1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Illinois.

f. Iowa Code §§ 553.1, et seq., with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Iowa.

g. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to Class Members which are Kansas residents.

h. Me. Rev. Stat. Ann. 10, §§, 1101 *et seq.,* with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Maine.

i. Md. Comm. Laws. Ann. §§ 11-204 *et seq.,* with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Maryland.

j. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Michigan.

k. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. §§ 8.31 *et seq.*, with respect to Class Members which are Minnesota residents.

l. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Mississippi.

m. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Nebraska.

n. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Nevada.

    i. In accordance with the requirements of Nevada Revised Statute § 598A.210(3) contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Aaron Ford, Attorney General of Nevada, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

o. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New Hampshire.

p. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New Mexico.

q. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of New York.

i. In accordance with the requirements of N.Y. Gen. Bus. L. § 340(5), contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Letitia James, Attorney General of New York, informing her of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

r. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of North Carolina.

s. N.D. Cent. Code Ann. §§ 51-08.1-01, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of North Dakota.

t. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Oregon.

u. R.I. Gen. Laws §§ 6-36-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Rhode Island.

i. In accordance with the requirements of R.I. Gen. Laws § 6-36-21, contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Peter Neronha, Attorney General of Rhode Island, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

v. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of South Dakota.

w. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Tennessee.

x. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Utah.

i. In accordance with the requirements of Utah Code Ann. § 76-10-3109 contemporaneously with the filing of this Complaint, counsel is sending letters by certified mail, return receipt requested, to: Sean Reyes, Attorney General of Utah, informing him of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

y. W.Va. Code §§ 47-18-1, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of West Virginia.

z. Wis. Stat. §§ 133.01, *et seq.*, with respect to Class Members that have issued prescriptions for Defendants' drug products within the state of Wisconsin.

272. Defendants' conduct had substantial intrastate effects. Covered entities in the 340B Program with Contract Pharmacy arrangements in place reside within each of the above-listed States and were denied or limited in receiving Contract Pharmacy 340B Drug Discounts from Defendants. Defendants' conspiracy caused those entities to pay inflated prices for Defendants' 340B Drugs and/or to lose 340B Savings at multiple Contract Pharmacies within each State, thereby threatening to reduce the healthcare services and discounts available to the covered entities' patients in each State. The continuing scheme to limit or eliminate Contract Pharmacy 340B Drug Discounts directly affects and disrupts commerce within each State.

THIRD CLAIM—STATE UNJUST ENRICHMENT
(Damages for overcharges)

273. Plaintiffs hereby repeat the allegations in the foregoing paragraphs as if fully set forth herein.

274. Defendants have benefited from the above-described conduct at the expense of Plaintiffs and the Class Members, and Defendants continue to retain those benefits under circumstances where it would be unjust to do so.

275. Specifically, Defendants have colluded to deprive Plaintiffs and the Class Members of access to Contract Pharmacy 340B Drug Discounts and have thereby improperly retained the value of those discounts for their own benefit and to the detriment of Plaintiffs and the Class Members. By engaging in this conduct, Defendants have met the elements of unjust enrichment in the following states specifically because:

a. Under Alabama common law, Defendants hold money that belong in equity and good conscience, to the Plaintiffs and retention of that money is unjust because Defendants engaged in collusion to receive that money;

b. Under Alaska common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;

c. Under Arizona common law, Defendants have been enriched by a benefit, Plaintiffs have been impoverished by not receiving the benefit, there is a relationship between the enrichment and the impoverishment, Defendants do not have an adequate justification for being unjustly enriched, and there is not an adequate remedy at law;

d. Under Arkansas common law. Defendants, through its collusion, unjustly received and is enriched by money to which it was not entitled and which caused detriment to the Plaintiffs;

e. Under California common law, Defendants have been unjustly enriched by a benefit at the expense of Plaintiffs and there is an underlying legal basis for receiver, specifically the antitrust violations at issue;

f. Under Colorado common law, Defendants received a benefit at Plaintiffs' expense and the Defendants collusion make it unjust for the Defendants to retain the benefit without commensurate compensation;

g. Under Connecticut common law, Defendants unjustly received and are enriched by money to which they were not entitled and which caused detriment to the Plaintiffs;

h. Under D.C. common law, Defendants unjustly received and are enriched by money to which they were not entitled and which caused detriment to the Plaintiffs;

i. Under Delaware common law, Defendants have been enriched by a benefit, Plaintiffs have been impoverished by not receiving the benefit, there is a relationship between the enrichment and the impoverishment, Defendants do not have an adequate justification for being unjustly enriched, and there is not an adequate remedy at law;

j. Under Florida common law, Plaintiffs conferred a direct benefit upon Defendants, Plaintiffs appreciated the benefit, Defendants also appreciated the benefit, and the circumstances, specifically Defendants' collusion, makes retention of the benefit inequitable without paying value for the benefit;

k. Under Georgia common law, Plaintiffs conferred a benefit upon Defendants, equity requires that the Defendants compensate the Plaintiffs for the benefit; and the parties did not have a legal contract;

l. Under Hawaii common law, Plaintiffs conferred a benefit upon Defendants and Defendants have unjustly retained that benefit as the expense of the Plaintiffs;

m. Under Indiana common law, Plaintiffs conferred a benefit upon Defendants at the express or implied consent of Defendants, allowing the Defendants to retain the benefit without restitution would be unjust, and Plaintiffs expected payment;

n. Under Illinois common law, Defendants have been enriched by the receipt of a benefit at the expense of the Plaintiffs and it would be unjust to allow Defendants to retain the benefits under these circumstances;

o. Under Iowa common law, Defendants have been enriched by the receipt of a benefit at the expense of the Plaintiffs and it would be unjust to allow Defendants to retain the benefits under these circumstances;

p. Under Kansas common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;

q. Under Kentucky common law, a benefit was conferred upon the Defendants at the Plaintiffs' expense under circumstances, specifically the collusion among Defendants, that make in unjust for Defendants to retain the benefit without paying for it;

r. Under Louisiana common law, Defendants were enriched, Plaintiffs were impoverished, there was a rational connection between enrichment and the impoverishment, there is a lack of justification for the enrichment, and there is an absence of any other legal remedy;

s. Under Maine common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;

t. Under Maryland common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;

u. Under Massachusetts common law, Defendants hold property, the circumstances dictated that in equity and good conscience, the Defendants ought not retain the property because of their collusion;

v. Under Michigan common law, Defendants have received a benefit and retention of that benefit would result in an inequity;

w. Under Minnesota common law, Defendants have unjustly received and retained a benefit that they are not entitled to and the Plaintiffs lack an adequate legal remedy at law;

x. Under Mississippi common law, there is no legal contract between Defendants and Plaintiffs, Defendants are in possession of money that, in good conscience

and justice, it should not retain, and Defendants should deliver the property to another;

y. Under Missouri common law, Plaintiffs conferred a benefit on Defendants, who recognize and accept that they have received a benefit, and the enrichment is unjust because of the Defendants' collusion;

z. Under Montana common law, a benefit was conferred upon Defendants to the detriment of Plaintiffs and Defendants are at fault or otherwise engaged in misconduct by colluding, Defendants took advantage of Plaintiffs;

aa. Under Nebraska common law, Defendants have unjustly received and retained a benefit that, in justice and fairness, they ought to return to Plaintiffs;

bb. Under Nevada common law, Defendants hold property, the circumstances dictated that in equity and good conscience, the Defendants ought not retain the property because of their collusion;

cc. Under New Hampshire common law, through their collusion or otherwise wrongful acts, unjustly received a benefit to the detriment of Plaintiffs such that it would be unconscionable for Defendants to retain the benefit;

dd. Under New Jersey common law, Plaintiffs conferred a benefit upon Defendants; retention of the benefit without payment would be unjust, and Defendants were enriched beyond their contractual rights;

ee. Under New Mexico common law, Defendants have knowingly benefited at Plaintiffs' expense and in a manner such that allowing the Defendants to retain the benefit would be unjust;

ff. Under New York common law, Defendants have been enriched at Plaintiffs' expense and permitting Defendants to retain the benefit conferred would be against equity and good conscience;

gg. Under North Carolina common law, Plaintiffs conferred a non-gratuitous benefit on the Defendants, who realized some value from the benefit, and it would be inequitable for Defendants to retain the benefit in light of Plaintiffs' impoverishment;

hh. Under North Dakota common law, Defendants were enriched, Plaintiffs were impoverished, there was a rational connection between enrichment and the impoverishment, there is a lack of justification for the enrichment, and there is an absence of any other legal remedy;

ii. Under Oklahoma common law, it would be inequitable, based on Defendants collusion, for them to retain the benefit received at the expense of Plaintiffs;

jj. Under Oregon common law, a benefit was conferred on Defendants, of which Defendants are aware, and, under the circumstances, it would be unjust to allow retention of the benefits without requiring the Defendants to pay for it;

kk. Under Pennsylvania common law, Plaintiffs conferred a benefit on Defendants, who appreciated or recognized the benefits, and the Defendants wrongfully secured, through their collusive acts, those benefits, such that it would be inequitable for Defendants to retain the benefits;

ll. Under Rhode Island common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, and it is inequitable for Defendants to retain the value of the benefit;

mm. Under South Carolina common law, Plaintiffs conferred a non-gratuitous benefit on the Defendants, who realized some value from the benefit, and it would be inequitable for Defendants to retain the benefit in light of Plaintiffs' impoverishment;

nn. Under South Dakota common law, a benefit was conferred on Defendants, of which Defendants are aware, and, under the circumstances, it would be unjust to allow retention of the benefits without requiring the Defendants to pay for it;

oo. Under Tennessee common law, Plaintiffs conferred a benefit upon Defendants, Defendants appreciated the benefit, it is inequitable for Defendants to retain the value of the benefit, and Plaintiffs have exhausted their remedies against Defendants or pursuit would be futile;

pp. Under Texas common law, Defendants, through their collusion or otherwise wrongful acts, unjustly received a benefit to the detriment of Plaintiffs such that it would be unconscionable for Defendants to retain the benefit;

qq. Under Utah common law, Plaintiffs conferred a benefit upon Defendants, Defendants have knowledge of the benefit, it would be unjust for Defendants to retain the value of the benefit, and Plaintiffs lack an adequate remedy at law;

rr. Under Vermont common law, a benefit was conferred on Defendants, who accepted the benefit, and, in light of the circumstances, equity and good conscience demand that Defendants return the benefit;

ss. Under Virginia common law, Plaintiffs conferred a benefit on Defendants, the Defendants knew of and accepted the benefit, the Defendants should reasonably be expected to repay the Plaintiffs; and the Plaintiffs do not have a remedy at law;

tt. Under Washington common law, Plaintiffs conferred a benefit on Defendants, who appreciated or had of the benefit, the retention by the Defendants of the benefit under such circumstances would be inequitable for the Defendants to retain the benefit, and the Plaintiffs do not have an adequate remedy at law;

uu. Under West Virginia common law, Defendants have received money, to which they were not entitled and the payment was a mistake on the part of Plaintiffs;

vv. Under Wisconsin common law, Plaintiffs conferred a benefit upon Defendants, Defendants have knowledge of the benefit, and it would be unjust for Defendants to retain the value of the benefit.

276. The financial benefits enjoyed by Defendants through the wrongful collusive conduct described above are directly traceable to the losses suffered by Plaintiffs and the Class Members from not having access to, or having limited access to, Contract Pharmacy 340B Drug Discounts because of Defendants' collusion.

277. Specifically, Defendants have colluded to deprive Plaintiffs and the Class Members of access to Contract Pharmacy 340B Drug Discounts and have thereby retained the value of those discounts for their own benefit and to the detriment of Plaintiffs and the Class Members.

278. The financial benefit enjoyed by Defendants through the wrongful collusive conduct described above are directly traceable to the losses suffered by Plaintiffs and the Class Members from not having access to, or having limited access to, Contract Pharmacy 340B Drug Discounts because of Defendants' collusion.

279. It would be inequitable under unjust enrichment principles for Defendants to be permitted to retain amounts derived from Defendants' unfair and unconscionable methods, acts, and trade practices of collusion as alleged in this Complaint, through any resulting overcharges.

JURY DEMAND

280. Plaintiffs request a jury trial of all issues triable of right by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

1. Certifying this action as a class action, certifying Plaintiffs as Class Representatives, and appointing Plaintiffs' counsel of record as Class Counsel, all pursuant to Rule 23 of the Federal Rules of Civil Procedure;

2. Declaring Defendants' conduct violated federal and State laws;

3. Awarding money damages in an amount to be proved at trial, plus statutory damages, punitive and treble damages, and other such relief as provided by law, together with all such further relief as may be just and proper, plus pre-judgment and post-judgment interest, to Plaintiffs and Class Members;

4. Awarding the costs of bringing this action, including reasonable attorneys' fees and expenses, as further provided by the statutes cited;

5. Entry of preliminary and permanent injunctive relief prohibiting the anticompetitive conduct alleged herein and eliminating the anticompetitive effects of the same, as well as providing any appropriate restitution and/or disgorgement of all unlawful or illegal profits received by Defendants as a result of the anticompetitive conduct alleged herein; and

6. Granting all other relief to which Plaintiffs and Class Members may be entitled at law or equity.

Dated: October 22, 2021

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